

# **Suspected Lung Cancer – Pathway to a Timely Diagnosis**

# Guidelines for the Diagnosis and Referral of Suspected Lung Cancer



Approved by Clinically Detected Lung Cancer Working Group: November, 2015 Endorsed by CCNS Clinical Standards Oversight Committee: December, 2015 Endorsed by CCNS Chief Operating Officer: December, 2015 Approved by NSHA VP Integrated Health Services, Program of Care 1 and Senior Leadership Team: June, 2016

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#### Introduction:

This guideline was developed by the Cancer Care Nova Scotia (CCNS) Clinically Detected Lung Cancer Working Group. A list of the multidisciplinary Working Group Members from across Nova Scotia is included at the end of this document.

The principle of this guideline is: the right people, right investigations, right diagnosis, right time.

The purpose of the guidelines is to:

- Streamline and speed the process of investigation and diagnosis of suspected lung cancer and referral for treatment leading to better patient outcomes.
- Enable patients to have their work-up as close to their home community as safely possible by working better with local resources.
- Enhance and improve care for lung cancer patients and their families across Nova Scotia.
- Consider issues identified by patients, survivors and families.

The guidelines have been written for health care providers in Nova Scotia based on current evidence, best practice and the Nova Scotia context. The Working Group adopted and/or adapted recommendations from other pathways and guidelines as appropriate for the Nova Scotia context. References are provided at the end of this document. Where issues of importance to the diagnosis and referral of lung cancer in Nova Scotia were not addressed by the references, the Working Group provided expert opinion. Unless otherwise specified, the recommendations were based on Working Group Consensus.

The main source documents used are outlined in the table below, with a full list of <u>references</u> provided at the end of this document. CCNS also conducted a focus group and online survey for lung cancer patients and family members to inform this work.

American College of Chest Physicians (ACCP)	2013	Diagnosis and Management of Lung Cancer, 3 <sup>rd</sup> edition
Cancer Care Manitoba	2014	Lung Cancer Pathway
Cancer Care Ontario	2012	Lung Cancer Diagnosis Pathway (and supporting documents from the Program in Evidence Based Care)
		documents from the Program in Evidence Based Care)
National Institute for Health and	2011	Lung Cancer: The diagnosis and treatment of lung
Clinical Excellence (NICE)		cancer

This document is meant to provide guidance and clarity to primary care providers and specialists for the diagnosis and referral of clinically suspected or incidentally detected lung cancer. These are not emergency guidelines. Oncologic emergencies should follow the Guidelines for the Management of Oncologic Emergencies in Adult Cancer Patients for management protocols.<sup>1</sup>

For the purposes of this document, family physicians, nurse practitioners and primary care collaborative teams are referred to as primary care providers (PCPs).

The recommendations are numbered and arranged in order of the patient journey through the diagnostic process. The numbers do not reflect the importance of the recommendations.

Guidelines or recommendations should never replace specific decisions for individual patients and do not substitute for the shared decisions between any patient and physician which are unique to each circumstance.

This guideline will be reviewed as new evidence emerges or every three years. Feedback on the guideline can be sent to: <a href="mailto:info@ccns.nshealth.ca">info@ccns.nshealth.ca</a>.

#### **Table of Contents:**

#### **Section I: Communication**

This section describes the general principles for good communication between patients and health care providers, as well as between health care providers themselves. This section is likely of interest to all health care providers.

- A. Patient-Provider Communication Principles
- B. Communication between Health Care Providers

# **Section II: Initial Investigation**

This section describes the signs and symptoms that may be seen when a patient first presents with suspected lung cancer, as well as the recommended initial investigations including chest x-ray. The role of primary care providers and the importance of communication with the patient are highlighted. This section is likely of interest to health care providers who see suspected lung cancer patients initially and radiologists.

- A. Initial Presentation
- B. Signs and Symptoms Requiring Investigation
- C. Chest X-ray
- D. Initial Presentation and Investigation Flow Chart
- E. Hemoptysis Flow Chart
- F. Role of Primary Care Provider during the Diagnostic Process
- **G. Smoking Cessation**

#### **Section III: Chest CT**

This section describes the clinical information that should be provided when booking chest CTs, suggested protocols based on chest x-ray results, appointment triaging and reporting timelines, as well as recommended chest CT report content and categories of lung abnormalities with suggested actions. This section is likely of interest to radiologists and health care providers who order chest CTs.

- A. Ordering
- B. Protocol and Booking
- C. Reporting and Recommended Actions

# **Section IV: Specialist Consult and Work Up**

This section describes which patients should be referred to a diagnostic specialist following chest CT. It also outlines work up investigations such as bronchoscopy, endobronchial ultrasound, and fitness for treatment testing. This section is likely of interest to diagnostic specialists including thoracic surgeons, respirologists and internists, and referring health care providers.

- A. Communication about Referrals and Decision Making
- B. Referral to Diagnostic Specialist for Consult and Further Investigations
- C. Bronchoscopy
- D. Endobronchial Ultrasound
- E. Physiological Assessment (Fitness for Treatment, including pulmonary rehabilitation)
- F. Cardiology Assessment

# **Section V: Biopsy and Laboratory Testing**

This section describes which patients should have a lung biopsy as well as the submission requirements of specimens for cytology, pathology, and molecular testing. This section is likely of interest to physicians who perform lung biopsies, and pathologists.

- A. Lung Biopsy
- B. Submission and Reporting of Lung Specimens for Cytology
- C. Submission and Reporting of Lung Specimens for Pathology
- D. Submission and Reporting of Lung Specimens for Molecular Testing

# **Section VI: Diagnosis**

This section describes the communication and supportive care needs of patients when they are given a diagnosis of lung cancer, including cancer patient navigation and screening for distress. This section is likely of interest to health care providers who are involved with patients at the time of diagnosis.

- A. Communication at the Time of Confirmation of Cancer Diagnosis
- B. Psychosocial and Supportive Care Referrals

# **Section VII: Additional Imaging for Staging**

This section describes the indications and important information about additional imaging for lung cancer staging. This section is likely of interest to radiologists and referring health care providers.

- A. PET
- B. Bone Scan
- C. Brain Imaging
- D. Other Staging Imaging

#### **Section VIII: Treatment Referral**

This section describes the considerations for initial treatment and timelines for referral of lung cancer patients to treatment specialists. This section is likely of interest to treatment specialists and referring health care providers.

- A. Decisions Based on Stage Information
- **B. Treatment Referral**
- C. Target Timelines for Treatment Initiation

# References

Appendix A: Clinically Detected Lung Cancer Working Group Members
Appendix B: Guideline Development and External Review Process

# **Section I: Communication**

Regardless of the type of cancer diagnosis, a consistent concern from cancer patients and their families is the need for clear, consistent communication.

# A. Patient-Provider Communication Principles

Investigation for a possible cancer is a stressful time for patients; there is an opportunity for miscommunication and escalating anxiety for patients as they await test results. It is important that all involved health care providers keep the patient informed throughout the diagnostic and treatment process.

# All health care providers who communicate with patients and families should:

- Be respectful of patients and their families and provide them with the information they need.
- Listen and respond appropriately to patient and family concerns and questions.<sup>2</sup>
- Communicate with patients and families using language and terms that they can easily understand.<sup>3,4</sup> Use the teach-back method to ensure patients and families understand the information given.
- Inform the patient when there is a strong suspicion of cancer not yet confirmed (e.g. imaging results), and of the next steps, including the expected wait time for results.<sup>3</sup>
- Be open and transparent with patients, such as sharing information contained in consult reports and referral letters.
- Use visual aids, such as the patient's own diagnostic imaging scans, to help explain test results.
- Allow time for patients to ask questions and respond appropriately.<sup>2,3,5</sup>
- Be aware of both verbal and non-verbal cues.<sup>6</sup>
- Be culturally and linguistically competent and responsive. <sup>2,5,4</sup> Be mindful of socioeconomic status.
- Ensure that the patient is not used as a go-between for information between health care providers. 2,3
- Utilize individualized communication.<sup>2,5</sup>
- Clarify the contact person to the patient and families and provide direction on how to contact.

# **B.** Communication between Health Care Providers

It is essential that referring health care providers provide the required information (as defined throughout this document) on all referrals to assist in appropriate triaging and interpretation of results. This includes communicating the reason for referral and level of suspicion for lung cancer.

Good communication and coordination between health care providers (primary care providers, emergency department physicians, and specialists) (clinical or diagnostic) are essential to a timely and accurate diagnosis. Primary care providers should not hesitate to directly contact specialists regarding questions.

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# **Section II: Initial Investigation**

# A. Initial Presentation

The primary care provider or other health care provider to whom the patient presents should investigate signs and symptoms of suspected lung cancer appropriately.

The primary care provider or other health care provider to whom the patient presents (e.g. emergency department physician) should:

- Inform the patient of the purpose of investigations ordered, what to expect, the importance of keeping appointments, and expected wait times.
- Provide symptom management as appropriate and counsel patients on when to seek medical attention for new or worsening symptoms (e.g. bone pain, shortness of breath, neurological symptoms).

#### **Clinical Risk Modifiers:**

The following factors are associated with an increased lifetime risk of lung cancer and should be included in patient assessments:

- Current or ex-smoker<sup>7,8,9</sup>
- COPD<sup>7,8,9</sup>
- Age > 50 years<sup>10</sup>
- Personal history of cancer or family history of lung cancer<sup>7,8,9</sup>
- Significant second hand smoke exposure<sup>7,8,9</sup>
- Exposure to asbestos or other known carcinogens (e.g. radon, chromium, nickel, radiation exposure)<sup>7,8,9</sup>
- Immunocompromised
- Occupational exposure to dust or microscopic particles (e.g. wood dust, silica)<sup>7,8,9</sup>
- Silicosis, tuberculosis<sup>7,8,9</sup>

It is important to recognize that lung cancers also occur in patients without apparent risk factors. For example, it is estimated that 10-15% of patients with lung cancer have never smoked. <sup>11</sup> In addition, while risk peaks in the eighth decade, age less than 50 years does not exclude lung cancer. <sup>10</sup>

A negative chest x-ray in patients with risk factors for lung cancer and persistent symptoms should be investigated further.

# **B. Signs and Symptoms Requiring Investigation**

# Signs and symptoms of lung cancer that require immediate referral to emergency department:

- Acute significant hemoptysis (e.g. 2 tbsp in one episode, 1 cup in 24 hours)<sup>7,8,9,12</sup>
- Suspected superior vena cava obstruction<sup>7,8,9</sup>
- Stridor/ symptomatic central airway obstruction<sup>7,8,9,12</sup>
- New neurological signs suggestive of brain metastasis or cord compression<sup>7,8,9</sup>
- Symptoms suggestive of paraneoplastic syndrome with severe metabolic disturbance (e.g. hyponatremia, hypercalcemia)<sup>12</sup>

# Signs and symptoms of lung cancer that require chest x-ray:

- Hemoptysis<sup>4,6,8,9,14</sup>
  - NOTE: Hemoptysis that persists without explanation should also be investigated by CT and referred to a specialist.
- Features suggestive of paraneoplastic syndromes<sup>6,7,8,9</sup>
- Supraclavicular lymphadenopathy<sup>6,7,8,9</sup>
  - NOTE: Persistent lymphadenopathy or lymphadenopathy without benign explanation should also be referred to a specialist. A normal chest x-ray should not preclude specialist referral.
- Unexplained/uninvestigated increase in dyspnea<sup>14</sup>
- Features of metastatic lung cancer<sup>6,8,9</sup>
  - o NOTE: This is a complex clinical assessment based on the history of the patient and the symptoms. Clinical judgment should be used.
- Unexplained cough persisting for more than 3 weeks\*<sup>4,6,7,8,9</sup>
- Unexplained hoarseness persisting for more than 3 weeks<sup>4,7,8,9,14</sup>
  - NOTE: Unexplained hoarseness persisting more than 3 weeks should be referred to an ENT or respirology specialist.
- Unexplained weight loss/ loss of appetite persisting for more than 3 weeks\*4,6,7,8,9
- Unexplained chest and/or shoulder pain persisting for more than 3 weeks\*4,6,7,8,9
- Uninvestigated/unexplained abnormal chest signs persisting for more than 3 weeks\*4,6,7,8,9
- Unexplained changes in existing symptoms in patients with underlying chronic respiratory problems persisting for more than 3 weeks\*<sup>6,8,9</sup>

Clinicians should have a high index of suspicion with a low threshold for investigation of suspected lung cancer when ordering chest x-rays and referring patients to lung cancer specialists. A normal chest x-ray should not be relied upon to exclude lung cancer, especially if the patient has clinical risk modifiers as listed above. Although most of these signs and symptoms will require chest CT, chest x-ray may identify an acute treatable illness, such as pneumonia or pulmonary edema. The results of the chest x-ray also help determine the CT protocol and urgency.

<sup>\*</sup>NOTE: Patients with known risk factors may be referred sooner.

# C. Chest X-Ray

# Required information to be included on chest x-ray requisition:

- Indications for chest x-ray (clinical history/presumed diagnosis)
- Smoking history (current smoker, past smoker, never smoked)
- Other diagnosed cancer (concurrent or prior; if prior, indicate disease free interval)
- Is there a strong clinical suspicion for a benign process (e.g. pneumonia)?
  - Presence or absence of infection within previous 6 weeks
- Referring health care provider's office number including afterhours contact information for urgent results
- Patient contact information

# Timeline for chest x-ray:

- Where chest x-ray is available on a walk-in basis, the primary care provider should emphasize the level of urgency for obtaining the chest x-ray to the patient. Patients are not contacted by radiology departments for walk-in exams.
- Where chest x-rays are available by appointment only, the primary care provider should follow the protocol for urgent chest x-rays in their area.

# Timeline for chest x-ray reporting:

- a) Emergency chest x-ray:
- 95% of emergency department chest x-ray cases should be reported within 24 hours of exam being performed.
- Every diagnostic imaging site should have a radiologist available 24/7 for more urgent reports (by telephone) when specifically requested.
- b) All other chest x-ray reporting should follow the Canadian Association of Radiologists (CAR) reporting guidelines:15
- 95% of <u>inpatient</u> imaging cases reported within 24 hours of exam being performed.
- 95% of outpatient imaging cases reported within 96 hours of exam being performed.
  - If the referring health care provider requires a more urgent report, this should be indicated on the requisition along with appropriate physician contact information including after hours contact information.

# Recommended chest x-ray report content:

- Degree of suspicion
- Comparison to previous chest x-rays as appropriate

# Recommended actions based on chest x-ray results:

NOTE: Normal chest x-rays are not exclusionary but may help guide next steps (e.g. different CT protocols following a negative versus abnormal chest x-ray).

- a) Negative chest x-ray with low suspicion of malignancy
  - Observe and manage as per clinical findings.<sup>7,8</sup>

- b) <u>Abnormal chest x-ray findings suggestive of infectious disease process</u> e.g. pneumonia (lung cancer not suspected)
  - Clinical context is crucial. Pneumonia and lung cancer can produce very similar findings on chest x-ray.
  - Follow up chest x-ray to confirm resolution is **generally not required unless clinically indicated** for patients under the age of 50 or at low risk for lung cancer.<sup>43</sup> If both chest x-ray and clinical assessment are typical for pneumonia, the likelihood of an underlying neoplasm is very low in patients under the age of 50.
  - For patients at high risk for lung cancer (e.g. advanced COPD) or unusual chest x-ray finding not fitting with pneumonia, follow up in 6 weeks with chest x-ray.

NOTE: Pneumonia is a clinical diagnosis, and is not based solely on chest x-ray.<sup>43</sup>

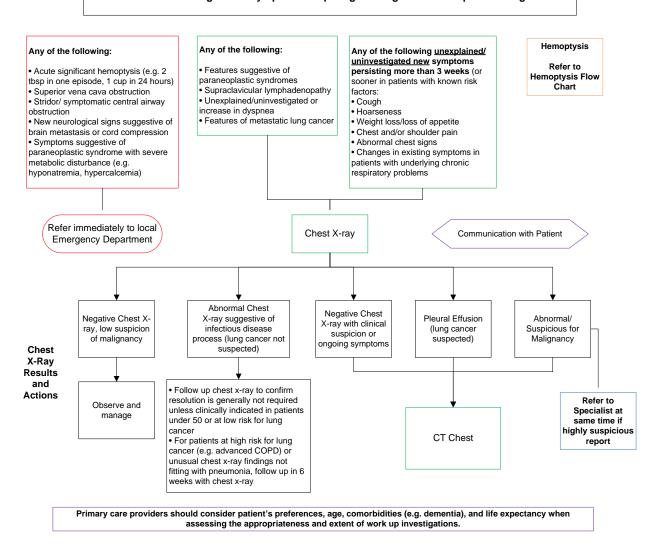
- c) Negative chest x-ray with clinical suspicion or ongoing symptoms
- Refer for CT chest. 6,7,8,9
- d) Pleural effusion on chest x-ray
- Obtain a CT chest to investigate persistent or unexplained unilateral pleural effusion or thickening and refer to a local specialist.
  - Image-guided or bed-side diagnostic or therapeutic thoracentesis can precede CT and/or specialist referral.<sup>16</sup>
    - If the effusion is malignant, some patients should be considered for molecular testing or clinical trials in consultation with thoracic surgery (see <u>Submission and</u> <u>Reporting of Lung Specimens for Molecular Testing</u>).

NOTE: Infectious pleural effusions need to be followed closely. If persistent, specialist referral recommended.

- e) Abnormal chest x-ray Suspicious for malignancy
- Refer for priority CT chest booking. 6,7,8,9,17
  - Degrees of urgency and timelines are outlined below (see <u>Chest CT Appointment</u> Triage).
- Refer to specialist at same time if highly suspicious report.<sup>4</sup>

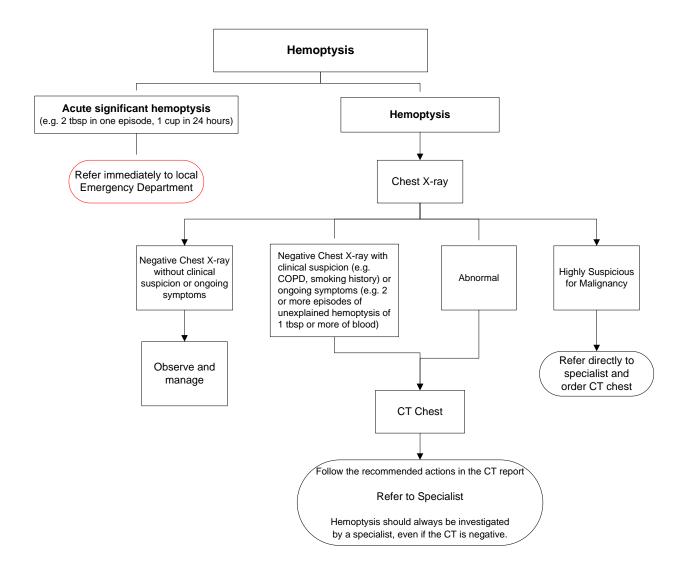
# D. Initial Presentation Flow Chart

Initial Presentation: Signs and Symptoms Requiring Investigation for Suspected Lung Cancer



# E. Hemoptysis Flow Chart

# Hemoptysis Flow Chart



# F. Role of Primary Care Provider During the Diagnostic Process

Primary care providers are often well suited to have ongoing conversations with their patients about their needs and concerns as they have already established a relationship of trust. Primary care providers should:

- Discuss the possibility of a cancer diagnosis.
- Explain the tests ordered and expected next steps.
- Discuss with patients how they would like to receive their test results (e.g. over the phone, with their family present).
- Be clear with patients about knowledge limitations and note when a specialist is better suited to address patient concerns.
- Schedule appointments to assess ongoing needs, review and explain test results, and provide support and supportive care referrals as necessary.
- Advise patients who smoke to stop smoking, explain the benefits of cessation, and refer to local smoking cessation services (see **Smoking Cessation**). 4,18
- Provide appropriate pain and symptom management during the investigative period until the patient is being followed by a specialist.
  - Worsening symptoms may require contact with specialist to expedite clinic appointment or treatment.
- Educate patients about when to seek appropriate medical attention (i.e. family physician, 811, emergency department) for new or worsening symptoms (e.g. bone pain, shortness of breath, neurological symptoms).
  - While waiting for initial specialist assessment, it may be necessary for the primary care provider to contact the specialist if signs and symptoms of lung cancer progress.
- Discuss personal directives with patients and appropriate involvement of family members in sharing of medical information/decision making.<sup>5</sup>

Patients with suspected lung cancer often experience both physical and psychosocial health needs that should be addressed as part of their diagnostic and treatment process.<sup>3</sup> Patients may benefit from referral (or self-referral) to their local Cancer Patient Navigator before a diagnosis of cancer is confirmed (see Psychosocial and Supportive Care Referrals).

# **G. Smoking Cessation**

Smoking cessation improves the prognosis of cancer patients.<sup>19</sup>

Health care providers should inform all patients of the potential benefits of smoking cessation even after a cancer diagnosis, regardless of stage or prognosis, including improved survival, treatment outcomes, and health-related quality of life, as well as decreased treatment related toxicity, drug side effects, surgical complications, disease recurrence, and secondary cancers. <sup>20</sup> It is important that patients receive smoking cessation advice from their health care providers as this has been shown to increase the likelihood that patients will try to quit and remain tobacco free.<sup>21</sup>

Currently (2015), there is variation in the smoking cessation services available throughout Nova Scotia. The provincial model is currently being reevaluated.

# **Smoking cessation:**

- Smoking status should be documented in the patient health record and updated at regular intervals. 20,22,23
- Advise patients to stop smoking, explain why quitting is important and discuss the risks of continued smoking. 4,18,23
  - Quitting smoking may lead to:
    - Better treatment response 19,21
    - Improved health-related quality of life, including improved breathing and increased energy<sup>18,21,22,23</sup>
    - Decreased lung cancer related symptoms<sup>22,23</sup>
    - Decreased treatment-related complications and toxicities 19,21
    - Decreased risk of cancer recurrence<sup>19</sup>
    - Decreased risk for second primary cancer<sup>19,22</sup>
  - Risks of continued use:<sup>21</sup>
    - Shorter survival
    - Reduced treatment effectiveness
    - Higher complication rates from surgery and slower recovery
    - Higher treatment-related toxicity from chemotherapy and radiotherapy
    - Increased risk of other serious ailments such as cardiovascular or respiratory disease
    - Increased risk of cancer recurrence
    - Increased risk of second primary cancer
- Refer patients suspected of or diagnosed with lung cancer to locally available evidence based smoking cessation services as appropriate, preferably a combination of counseling and smoking cessation medications.<sup>20,22</sup>
- Encourage smoking cessation as far in advance as possible before initiating cancer treatment<sup>20</sup> but do not postpone surgery for lung cancer to allow patients to stop smoking.<sup>4,18</sup>
- Discuss smoking relapses and provide guidance and support to encourage continued smoking cessation attempts.<sup>20</sup>
- Smoking cessation should be integrated throughout the diagnostic and treatment process.<sup>21</sup>

NOTE: These recommendations may not apply to Stage IV lung cancer patients, particularly those who are close to end of life.

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# Section III: Chest CT

# A. Ordering

#### **Chest CT contraindications:**

- Unmanageable claustrophobia
- Patient weight exceeds scan table limit (maximum varies by manufacturer and model)

# Ordering health care providers for chest CT:

CTs can be ordered by primary care providers or specialists in Nova Scotia.

# Required information to be included on chest CT requisition:

- Risk factors for lung cancer
- Personal history of malignancy
  - o Concurrent or prior cancer. If prior, indicate disease free interval.
- **Symptoms** 
  - o Including presence or absence of infection within the previous 6 weeks
- For CT exams ordered to follow up on chest x-ray findings, the indication prompting the original chest x-ray should be included
- Contrast enhanced chest CTs require recent creatinine levels. If one is not available, order at same time as submitting CT referral. Emergent CTs should not be delayed pending this result.

# Information to be gathered from patient by the radiological technologist before chest CT performed:

The following information should be obtained from the patient prior to chest CT in order to provide radiologists with adequate clinical information to estimate lung cancer risk:

- Have you ever smoked?
  - o If yes, how many years?
  - o Average number of packs per day?
  - o If this is difficult to ascertain, determine more or less than 20 pack years total (the number of packs of cigarettes smoked per day multiplied by the number of years the person has smoked)
- Have you or your spouse ever been exposed to asbestos in your work?
- Have you ever had a cancer?
  - o If yes, what type?
- Have you ever had radiation therapy to your chest?

NOTE: This questionnaire and process has been in use since 2009 at the QEII with good results.

# B. Protocol and Booking

# Chest CT protocol for investigation of suspected lung cancer:

The CT protocol for individual patients will be determined by a radiologist using clinical and imaging history.

- a) Known lung cancer or chest x-ray highly suspicious: Enhanced\* CT chest and upper abdomen (for staging). 4,6,7 Give IV contrast. No need for oral contrast. Pelvis does not need to be included routinely.
- b) Evaluation of pleural effusion: Enhanced\* CT chest.<sup>7</sup>
- c) Evaluation of mediastinal mass or hilar/mediastinal nodal enlargement: Enhanced\* CT chest. 7
- d) <u>Evaluation of equivocal chest x-ray abnormality</u> (e.g., possible small nodule versus artifact): Low dose unenhanced CT chest.
- e) <u>Indeterminate nodule requiring surveillance</u>: Low dose unenhanced CT chest (not for staging).<sup>24</sup> Surveillance of nodules less than 1cm should be performed with 1 or 2mm imaging.
- f) <u>Negative chest x-ray with clinical suspicion of lung cancer</u>: Low dose unenhanced CT chest (not for staging).
- \*NOTE: For patients with contrast allergies or high risk of contrast induced nephropathy, an unenhanced CT is often sufficient. However, the liver cannot be staged on an unenhanced exam and may require ultrasound.

#### **CT Protocol for Investigation of Suspected Lung Cancer** CT protocol for individual patients will be determined by a radiologist using clinical and imaging history. Known lung Negative CXR with Indeterminate Evaluation of Mediastinal mass Pleural effusion cancer or chest clinical suspicion equivocal chest or hilar/mediastinal nodule requiring (lung cancer x-ray highly nodal enlargement of lung cancer surveillance x-ray abnormality suspected) suspicious Low dose Enhanced\* CT Low dose Low dose unenhanced CT Enhanced\* CT Enhanced\* CT chest and upper unenhanced CT unenhanced CT chest (surveillance chest chest abdomen (IV chest chest contrast) of nodules less than 1cm should be performed with 1 or 2mm imaging) \*For patients with contrast allergies or high risk of contrast induced nephropathy an unenhanced CT is often sufficient, however the liver cannot be staged on an unenhanced exam and may require ultrasound.

# **Chest CT appointment triage:**

The following priority levels and timelines are recommended for booking chest CT appointments: 15,25

- a) Maximum 24 hours (CAR priority level 1)
- Possible airway compromise (e.g. stridor)
- Severe hemoptysis
- Symptomatic SVC compromise
- Maximum 14 days (radiologists can code as CAR priority level 3, but specify "within 2 weeks")
- Initial staging of known tumor
- Hilar lymphadenopathy (high suspicion of malignancy)
- Mediastinal mass (especially if high suspicion of malignancy)
- Pleural effusion of unknown etiology (e.g. not explained by pneumonia, trauma, PE)
- Characterization of nodule/mass on chest x-ray (high suspicion chest x-ray OR high risk patient)
- Non-resolving consolidation
- Pre-op or pre-biopsy evaluation of lung mass
- Other high clinical suspicion of cancer (e.g. unexplained weight loss, new persistent cough in smoker)
- Suspected cancer growth or recurrence of treated cancer (routine follow up is usually "specified procedure date", see below)
- c) Maximum 30 days (CAR priority level 3)
- Hilar lymphadenopathy (low suspicion of malignancy)
- Hemoptysis (not severe, low risk malignancy)
- Characterization of sub centimeter pulmonary nodule or nodule vs. artifact on chest x-ray or non-chest CT (e.g. incidental nodule at lung base on CT abdomen) in a non-high risk patient
- d) Maximum 60 days (CAR priority level 4)
- Lung cancer screening (NOTE: Nova Scotia is currently investigating an organized lung cancer screening program for individuals at high risk.)
- e) Specified procedure date
- Referring health care provider should indicate if appointment is to coincide with a clinic visit.
- Radiologist should write on the requisition "specified procedure date" or "SPD" for appropriate triaging and wait time reporting.
- Examples of specified procedure date:
  - Follow up of pulmonary nodule at specified interval
  - o Appointment to coincide with clinic visit
  - Routine post oncology treatment

# C. Reporting and Recommended Actions

# **Timeline for chest CT reporting:**

- a) Emergency chest CT:
- 95% of emergency department chest CT cases should be verbally reported within 12 hours with the final written report within 24 hours of exam being performed.
- Every diagnostic imaging site should have a radiologist available 24/7 for more urgent reports (by telephone) when specifically requested.
- b) All other chest CT reporting should follow the Canadian Association of Radiologists (CAR) reporting guidelines:15
- 95% of <u>inpatient</u> imaging cases reported within 24 hours of exam being performed.
- 95% of outpatient imaging cases reported within 96 hours of exam being performed.
  - If referring health care provider requires a more urgent report, this should be indicated on the requisition.

# Same day chest CT reporting:

- The need for same day reporting in select cases must be clearly indicated on the requisition.
- Appropriate contact information, including afterhours contact information, for the referring health care provider must be provided.

# **Recommended chest CT report content:**

The Working Group recognizes that reporting styles vary amongst radiologists. Structured reporting (e.g. synoptic reporting) is an option, but no standard template is universally accepted at the time of writing.

The following report content is recommended in addition to the baseline of "radiological findings":

- Indication
  - o For the current CT exam and, if following up a chest x-ray abnormality, the indication for the index chest x-ray.
- Comparison studies
  - Indicate the most recent and most remote comparison utilized.
  - o This can become important if other relevant CTs not reviewed become available later.
- **Impression** 
  - o Indicate the most significant finding and any actionable findings.
  - For possible/probable lung cancer, the degree of concern raised by the CT findings should be expressed.
  - Highly suspicious findings should be emphasized (e.g. this lesion will remain worrisome even if PET or biopsy is negative).
- Exam limitations, if present and relevant to diagnostic certainty, should be noted.
- A "Next Step" recommendation is appropriate, most often being "referral to local thoracic specialist" or "follow up CT" in a specified interval.
- Directives regarding biopsy or PET should generally be avoided in the radiology report. Information pertinent to such decisions is often not available to the radiologist at the time of reporting.

# **Communicating chest CT results:**

- Verbal report may be appropriate when:
  - CT reveals a major unexpected finding likely to impact morbidity or mortality (e.g., pneumothorax, new collapsed lung, new large pleural effusion, SVC compromise, obstruction of main or lobar bronchus, pulmonary embolism, pericardial effusion).

# Categories of CT lung abnormalities and suggested actions:

This section relates to pulmonary nodules or masses, either symptomatic or incidental. Other abnormalities, which may be encountered during CT of the chest +/- abdomen, are beyond the scope of this document. Clinical circumstances may occur that supersede these recommendations, which are meant to enhance and not restrict decision making.

# a) Nodules <10 mm and not enlarging

- Radiologists should recommend a specific follow up interval.
- <u>Suggested action for nodules <10mm</u>: Manage as per radiology guidelines (e.g. Fleischner or other appropriate guidelines). <sup>26,27</sup>

NOTE: These nodules do not usually require specialist referral. Many nodules will require no action; some will require low dose unenhanced surveillance CT depending on nodule size and density, patient risk and age.

# b) Nodules > 10mm OR any size growing nodules and masses classify as:

#### Possibly transient

- CT findings with imaging and/or clinical features reasonably explained by inflammation or infection.
- Suggested action for possibly transient nodules: Reassess by low dose CT in 4-12 weeks depending on degree of concern.

# Benign

- o CT features are benign (e.g. calcified granuloma, hamartoma, round atelectasis, benign pattern of calcification, solid nodule stable for 2 years).
- o Suggested action for benign nodules: Discharge from imaging follow up.

#### Indeterminate

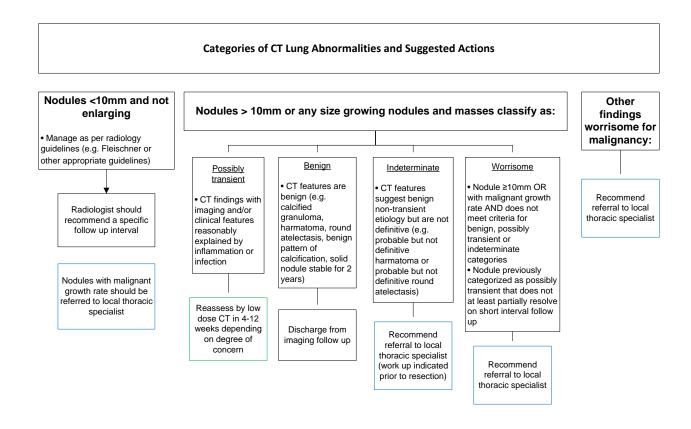
- o CT features suggest benign non-transient etiology but are not definitive (e.g. probable but not definitive hamartoma or probable but not definitive round atelectasis).
- Suggested action for indeterminate nodules: Refer to local thoracic specialist (for work up or serial CT).

# Worrisome

- 1. Nodule ≥10mm OR with malignant growth rate AND does not meet criteria for benign, possibly transient or indeterminate categories above.
- Nodule previously categorized as possibly transient that does not at least partially resolve on short interval follow up.

Examples of worrisome nodules include:

- Persistent solid or subsolid nodule ≥10mm.
- Baseline or enlarging well-defined lobulated or spiculated nodule ≥10mm with no recent pulmonary infection, trauma or pulmonary embolus.
- Solid nodule or solid portion of nodule enlarging with doubling time of 30-400 days.
- Suggested action for worrisome nodules: Refer to local thoracic specialist. Work up and treatment planning will depend on patient and nodule characteristics, including size and density. While not all worrisome nodules will require immediate treatment, referral to specialist is recommended for discussion.
- c) Other findings worrisome for malignancy:
- Other CT features worrisome for malignancy (e.g. lobar atelectasis without benign explanation, lymph node enlargement without benign explanation, mediastinal mass, pleural mass, nonresolving consolidation).
- <u>Suggested action for other findings worrisome for malignancy</u>: Refer to local thoracic specialist urgently.



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# Section IV: Specialist Consult and Work Up

# A. Communication about Referrals and Decision Making

# Referral for Diagnostic Tests and Procedures and/or Specialist Consult:

Providing patients with information about the diagnostic tests and procedures ordered for them can reduce their emotional distress and improve their psychological and physical recovery. However, health care providers should be cautious about providing information outside of their area of specialty.

# The referring health care provider should explain:

- The need to rule out a potential cancer diagnosis
- The purpose of the investigations ordered<sup>5</sup>
- The importance of keeping the appointment and expected wait times
- Information about what the patient is likely to experience before, during and after the procedure<sup>5</sup>
- The expected next steps
- When to seek medical attention for new or worsening symptoms (e.g. bone pain, shortness of breath, neurological symptoms)

#### Decision making and goals of care considerations:

- Each patient's personal preferences, age, comorbidities (e.g. dementia), and life expectancy should be considered when assessing the appropriateness and extent of further (potentially invasive) work up and when making treatment recommendations.<sup>24</sup>
- Conversations with the patient and decisions made should be documented and shared with involved health care providers.

# B. Referral to Diagnostic Specialist for Consult and Further Investigations

**Purpose:** The patient is seen by the diagnostic specialist (thoracic surgeon or respirologist) and evaluated to establish a clinical diagnosis and stage. The diagnostic specialist will choose the most appropriate diagnostic procedure(s) customized for each patient that may include: biopsy, additional imaging, fitness for treatment, and other investigations (e.g. bronchoscopy, EBUS).

Based on results of the diagnostic work up, the diagnostic specialist will refer the patient to a treating specialist(s) (thoracic surgeon, medical or radiation oncologist) or back to their primary care provider as appropriate. The primary care provider may refer the patient to palliative care if needed.

#### **Blood work:**

- Primary care providers should order blood work at the time of referral to specialist so results are available for the specialist consult.
  - o CBC, liver enzymes (ALK PHOS), calcium, INR, PTT, creatinine, sodium (SIADH)<sup>7,13</sup>

# Referral to diagnostic specialist:

# a) Refer to either Thoracic Surgery or Respirology:

- Central lesions
- Indeterminate or worrisome nodules (see <u>Categories of CT lung abnormalities and suggested</u> actions)
- Patients with high suspicion mediastinum on CT

# b) Refer to Thoracic Surgery:

- Surgical candidates
- Isolated mediastinal abnormalities

# c) Refer to Respirology:

- Abnormal CT results suspicious of anything except cancer (e.g. granulomatous disease)<sup>14</sup>
- Surgical candidates in need of optimization
- Non-surgical candidates
  - o Poorly controlled or advanced lung disease
  - Significant medical comorbidity, such as poor lung function
  - o Patient choice

NOTE: Any patient with significant respiratory symptoms limiting activities of daily living, significant abnormal pulmonary function on PFT testing, interstitial lung disease combined with a suspicion of cancer, or when diagnosis is in question and lung cancer is not highly suspected should be seen by a respirologist.

#### **Pleural Effusion:**

#### a) Primary Care Provider

• Refer to local specialist (e.g. respirology, interventional radiology, thoracic surgery, general internists) for assessment for thoracentesis. 4,6

# b) Diagnostic Specialist

- If concerning pleural effusion in a high risk patient, perform thoracentesis and assess for:
  - Transudative vs. exudative (LDH, total protein on blood and pleural fluid)
  - Cytology
  - o Cell count
  - Aerobic and anaerobic cultures
- If exudative effusion with no etiology found in a high risk patient, then refer to thoracic surgery for pleuroscopy, biopsy and molecular testing regardless of cytology result.

#### **Referral to Diagnostic Specialist Not Required:**

 Patients with low risk nodules do not need to be referred to a specialist (i.e. non-enlarging nodules <10mm, benign nodules, possibly transient nodules; refer to <u>Categories of CT lung</u> <u>abnormalities and suggested actions</u>).

# C. Bronchoscopy

# **Indications for Bronchoscopy:**

- Central lesions<sup>4,13,16</sup>
  - o Central is defined as the medial half of the chest field (50%)
- Lesions with a high suspicion of a positive bronchoscopy
- Lesions with possible consolidated mucinous adenocarcinoma
  - This can look like growing pneumonia; need to indicate suspicion of consolidated mucinous adenocarcinoma on requisition.
  - o Pathology needs to be informed so that they can look for those cells.
- All patients having surgery should have bronchoscopy (may be concurrent).
- Patients who have lesions with a high suspicion of a negative bronchoscopy should still be referred to a diagnostic specialist. The low concern for lung cancer should be communicated to the patient by the referring health care provider.

# Performing bronchoscopy:

- Bronchoscopies should be performed by physicians with formal training in bronchoscopy, such
  as a thoracic surgeon or respirologist, and are credentialed for this procedure by the Nova Scotia
  Health Authority.
- Special consideration may be given to other physicians to perform bronchoscopies in geographical areas of need who can demonstrate proficient and appropriate use of procedural skills, both diagnostic and therapeutic as required by the Royal College of Physicians and Surgeons of Canada (RCPSC).<sup>28</sup>
- Timely access to endoscopy suite or operating room with adequate infrastructure to process samples appropriately is required.
- A reasonable volume per year is needed to maintain competency. The American College of Chest Physicians recommends 25 bronchoscopy procedures per year.<sup>29</sup>

#### **Bronchoscopy procedure:**

- Endobronchial lesions should be biopsied:
  - o All patients with visible tumors should be biopsied.
  - o A minimum of 5 separate biopsies from a single visualized lesion should be taken.<sup>30</sup>
- In the absence of a visible lesion, bronchial washings should be performed.

#### Timeline for bronchoscopy appointment:

• In cases with a suspicion of cancer where bronchoscopy is indicated, it should be performed within 1-2 weeks from the decision to perform bronchoscopy.

#### **Triaging bronchoscopy:**

• Suspicion of cancer needs to be indicated on the referral form (e.g. include key words such as hemoptysis, central lesion, air bronchogram).

# **Bronchoscopy Reporting:**

Province wide synoptic reporting for bronchoscopy is under development.

# D. Endobronchial Ultrasound (EBUS)

EBUS-FNA will be available in Nova Scotia at the QEII Health Sciences Center in the near future.

#### Indications for EBUS-FNA:

- EBUS-FNA is recommended as the first choice procedure to assess the mediastinum:
- Mediastinal lymph node enlargement seen on CT<sup>4,18</sup>
  - o Defined as greater than 1cm on short axis
- Mediastinal lymph nodes positive on PET<sup>13,18</sup>

# Information required on EBUS-FNA referral:

- Reasons for referral are required for appropriate triage
- Use of anticoagulants
- Clotting status (INR, PTT)
- Renal function

# Ordering physicians for EBUS-FNA:

Any specialist (thoracic surgeon, respirologist, oncologist)

# **Performing EBUS-FNA:**

- EBUS-FNA is only performed by physicians with formal training.
- A reasonable volume per year is needed to maintain competency. The American College of Chest Physicians recommends 20 EBUS-FNA procedures per year.<sup>29</sup>

# **Timeline for EBUS-FNA appointment:**

Ideally, within 2 weeks of receipt of referral.

# E. Physiological Assessment (Fitness for Treatment)

#### Ordering health care providers for physiological assessment:

Primary care providers and specialists

#### Information required on referral for physiological assessment:

- Suspicion for cancer
- Sense of urgency

NOTE: It is important that all patients be screened for limited life expectancy from other comorbidities to prevent inappropriate surgery or unnecessary treatment.

# Refer for physiological assessment:

- All patients being evaluated for surgery or radiation therapy:
  - Pre and post bronchodilator spirometry and diffusion capacity<sup>31</sup>
- Patients being considered for chemotherapy:
  - Ejection fractions (at the discretion of the medical oncologist)

- Patients being considered for radiotherapy with curative intent:
  - Pulmonary function testing<sup>4</sup> (i.e. spirometry and diffusing capacity; lung volumes are not required)
- Surgical patients with **borderline physiological assessment** results should be referred to QEII thoracic surgery or respirology for services not available elsewhere.

# Timeline for physiological assessment testing appointment:

- Spirometry and diffusion- 2-3 weeks from receipt of referral by respirologist
- VO2 max- 3 weeks from receipt of referral by respirologist
- Ejection fractions- 2-3 weeks from receipt of referral by specialist

# Physiological assessment testing reporting:

Surgical risk level for lung cancer

NOTE: Cardiopulmonary exercise testing (CPET) is a pre-operative assessment tool that helps provide information on the relative risk associated with surgical intervention, e.g. high risk for major surgical intervention (lobectomy or greater). The CPET report will not state whether the patient should or should not have surgery. Surgical techniques evolve and lesser surgical interventions may still be possible and better than no surgical intervention or individuals may merit consideration for combined lung volume reduction surgery and tumor excision. Hence the information from it needs to be incorporated into that individual's overall best treatment option.

# **Pulmonary rehabilitation:**

- High risk patients undergoing surgery should be referred for pulmonary rehabilitation, both preoperatively and post-operatively.<sup>31</sup>
- Pre-operative pulmonary rehabilitation should not delay surgery.

# F. Cardiology Assessment

#### **Indications for cardiology assessment:**

- Recommended for patients with symptomatic cardiac conditions or other clinical concerns, who are potential candidates for surgery or chemotherapy. 4,31
  - Cardiology assessment is not routinely recommended if the patient has no significant cardiovascular disease and is not treated by cardiotoxic agents.
- Baseline ECG should be ordered by the treating specialist as appropriate

#### Timeline for cardiology assessment appointment:

- This should be completed within 2 weeks of receipt of referral.
- Priority for cancer treatment needs to be indicated on the referral form.

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# **Section V: Biopsy and Laboratory Testing**

# A. Lung Biopsy

# **Percutaneous Lung Biopsy**

Transthoracic needle biopsy (TNB) refers to radiological guided biopsy of a lung nodule or mass, most commonly using computed tomography.

Not all nodules or masses will require TNB. Some scenarios are better addressed by bronchoscopy or surgery and certain patients are unlikely to benefit from any biopsy.

The decision to perform a TNB should therefore occur as a part of a multidisciplinary conference or at a minimum as a consultation between a specialist (e.g. thoracic surgeon, respirologist or oncologist) and radiologist. For the same reasons, it is preferred that radiologists not directly recommend TNB in diagnostic imaging reports and instead recommend specialist referral for suspicious pulmonary nodules or masses.

# **Principles**

Underlying principles guiding TNB in suspected lung cancer include:

# a) Clinical Need

• A tissue diagnosis is germane to therapeutic decision making.

#### b) Safety/Path of Least Resistance

- Choose the relevant lesion which is most readily and safely accessible.<sup>13</sup>
- Have mechanisms in place to recognize and treat complications appropriately.
- Consultation with expert radiologists may be appropriate for certain highly challenging lesions.

#### c) Staging

• If applicable, choose the lesion most likely to upstage the patient. <sup>13</sup>

#### d) Single Procedure

 Sufficient tissue should be obtained for pathological and molecular diagnosis during one procedure.

# **Cytology versus Histology**

As of 2015, there is no consensus in the literature as to whether fine needle aspiration biopsy (FNAB) for cytology or core needle biopsy (CNB) for histology provides better accuracy for pathological diagnosis of malignancy, superior material for molecular analysis, or a more favourable complication rate. The type of needle used will therefore typically be the choice of the individual radiologist

performing the biopsy while adhering to the principles above (also see Molecular Analysis and Special Considerations, below).

# **Molecular Analysis**

It is now recognized that non small cell lung cancer (NSCLC) is an umbrella term for a genetically diverse family of tumours, many of which have mutations that are relevant to treatment and prognosis. Tumour genotyping through molecular analysis has thus become necessary for management of NSCLC patients in oncology.

For core biopsy technique, a single robust sample in formalin may be sufficient for both histology and molecular testing; however, more than one sample is preferred.

For FNA technique, as of 2015, an aspirate separate from the cytological sample is required and must be placed in formalin (see submission requirements for lung FNA specimens).

It is recognized that the circumstances of a particular biopsy procedure may limit the number of samples obtainable.

#### **Special Considerations**

In some cases the surgeon may prefer to do a surgical biopsy instead of a percutaneous biopsy. 24,32,33

TNB is not currently recommended for pure ground glass opacities.<sup>27</sup>

Mixed density nodules must have a solid component of sufficient size to target for biopsy.

Core biopsy may be preferred:

- a) In patients unlikely to undergo surgery as it is likely to yield greater material for ancillary testing.
- b) In the biopsy of metastases to allow for ancillary testing.
- c) When a specific benign diagnosis is required to be proven in an indeterminate nodule or mass.

FNA results of "Negative for malignancy" or "Inconclusive" do not exclude a lung cancer diagnosis. <sup>16,24</sup> These patients may require repeat TNB or alternate procedures or be subject to high level surveillance, depending on clinical circumstances.

# Information required on lung biopsy requisition:

- Anatomical location and the site of the lesion
- Reason for biopsy
- Degree of urgency and rationale
- To specifically request CNB or FNAB, indicate rationale
- Coagulation modifiers, especially warfarin, direct thrombin inhibitors, ASA and other antiplatelet agents (e.g. Plavix)
- Clinical history, particularly:<sup>34</sup>
  - History of cancer
  - Suspected diagnosis (primary, metastatic, non-small cell lung cancer, small cell lung cancer)

- Previous treatment
- Smoking history

# Timeline for lung biopsy booking:

• Lung biopsies should be performed within 2-3 weeks of receipt of referral

# B. Submission and Reporting of Lung Specimens for Cytology

#### Indications for sputum cytology:

- Sputum cytology is rarely indicated and should be reserved for the investigation of patients who have centrally placed nodules or masses and are unable to tolerate, or unwilling to undergo, bronchoscopy or other invasive tests.<sup>4,16</sup>
- If small cell lung cancer is suspected based on clinical and radiographic features.
  - o If sputum cytology results are positive for non-small cell lung cancer, further testing for adequate tissue sampling for biomarkers is needed.

# Information required on requisition or specimen container for lung cytology specimens (FNA lung, bronchial washing, bronchial brushing, sputum, or pleural effusion):

- Specimen type<sup>35</sup>
- Anatomical location and side of the lesion
- Date and time of specimen collection<sup>35</sup>
- Type of fixative
- Time of specimen fixation
- Clinical history:<sup>34</sup>
  - History of cancer
  - Suspected diagnosis (primary, metastatic, non-small cell lung cancer, small cell lung cancer)
  - Previous treatment
  - Smoking history
- Radiologic findings<sup>34</sup>

This information is required and will be incorporated into the cytology synoptic reporting template for lung specimens (in development).

# Submission requirements for bronchial washings, brushings and sputum:

- Ethanol or methanol based fixatives should be used (according to the individual cytology laboratory) or specimens may be submitted fresh if transport will not be delayed.
- Formalin should not be used a fixative for cytology specimens.

# Submission requirements for pleural fluid:

- Pleural fluid should be divided into 2 separate specimens, each with their own fixative:
  - Cytology fixative (cytology)
  - Formalin (IHC and molecular testing)
- Pleural fluid may also be submitted fresh if transport will not be delayed.

# Submission requirements for lung FNA specimens:

- Lung FNAs should be divided into 2 separate specimens, each with their own fixative:
  - Cytology fixative (cytology)
  - Formalin (cell block, IHC, molecular testing)

# **Submission requirements for EBUS specimens:**

- EBUS FNAs should be divided into 2 separate specimens, each with their own fixative:
  - Cytology fixative (cytology)
  - o Formalin (cell block, IHC, molecular testing)

# **Cell block preparation:**

 Cell blocks should be prepared on all lung cytology specimens (except for sputum) after cytology slides have been made when there is sufficient material to do so. 34,36

# Lung cytology reporting requirements:

- A quality statement about the specimen (cellularity, fixation) should be included in the cytology report.
- Specimens considered to be non-representative of the stated tissue site should result in a report that indicates such concerns.<sup>35</sup>

A cytology synoptic reporting template for lung specimens is under development.

# C. Submission and Reporting of Lung Specimens for Pathology

# Information required on requisition for lung pathology specimens:

- Specimen type<sup>35</sup>
- Anatomical location and side of the lesion
- Date and time of specimen collection<sup>35</sup>
- Type of fixative
- Time of specimen fixation
- Clinical history: 34
  - History of cancer
  - Suspected diagnosis (primary, metastatic, non-small cell lung cancer, small cell lung cancer)
  - o Previous treatment
  - Smoking history
- Radiologic findings<sup>34</sup>

This information is required and will be incorporated into the pathology synoptic reporting template for lung specimens (in development).

# Core biopsy specimen submission:

Each core biopsy specimen should be submitted and embedded separately.

# Lung pathology specimen reporting:

 Although reporting times vary depending on the complexity of the case, in general, pathology reports should be available in 3 weeks.

A pathology synoptic reporting template for lung specimens is under development.

# D. Submission and Reporting of Lung Specimens for Molecular Testing

# Order molecular testing:

- Molecular testing is suggested for early stage lung adenocarcinoma<sup>36</sup>
- Molecular testing is recommended for late stage lung adenocarcinoma<sup>36</sup>

# Do not order molecular testing:

- Molecular testing is not indicated for the following cases:
  - Neuroendocrine carcinomas<sup>36</sup>
  - o Squamous cell carcinomas<sup>36</sup>

# Specimen type required for molecular testing:

Biopsy and surgical specimens<sup>36</sup>

# Fixation requirements for molecular testing:

• Specimens must be submitted in formalin<sup>36</sup>

# Reporting timeline for molecular testing:

• 3 weeks from receipt of specimen by molecular testing lab

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# **Section VI: Diagnosis**

# A. Communication At the Time of Confirmation of Cancer Diagnosis

# **Communication by Diagnosing Physician**

# With the patient:

- It is the responsibility of the physician making the diagnosis to clearly communicate the diagnosis to the patient. Use the word "cancer" instead of synonyms such as "tumour" or "mass".<sup>3,5</sup>
- Patients should be informed of their diagnosis at the earliest appropriate time, ideally in a supportive environment.
- Patients should be given written information including their diagnosis, expected immediate next steps and timelines, the contact information of their local Cancer Patient Navigator and the lung cancer patient information kit (under development).
- All cancer patients should be referred to their local Cancer Patient Navigator.
  - o NB: There currently is no Cancer Patient Navigator in the Central Zone.
- Health care providers should assist patients and their families in interpreting and understanding the diagnosis and potential outcomes.
- Patients should be given realistic information and expectations about their diagnosis to facilitate informed decision making.<sup>4</sup> This should be an iterative, ongoing process.

#### With the primary care provider:

- The diagnosing physician will also inform the patient's primary care provider of the diagnosis, tests ordered, and the next steps.
- An interim typed note should be faxed to the primary care provider from the diagnosing specialist with this information so the primary care provider will have it before the patient's next appointment.

# **Primary Care Provider Communication with Patient:**

This may also be a good time for primary care providers to raise discussion of advance care planning, including personal directives, and appropriate involvement of family members in sharing of medical information and/or decision making.<sup>5</sup> Primary care providers should encourage patients to reflect on their values and what is important to them in terms of their goals of care. This will help guide treatment decision discussions at a later date.<sup>37</sup>

# **B.** Psychosocial and Supportive Care Referrals

# **Cancer Patient Navigator**

The Cancer Patient Navigator (CPN) is uniquely positioned to support cancer patients and their families throughout the continuum of care. They are oncology nurses that provide cancer patients and their families support throughout the cancer journey. Proactive interventions by navigators improve patient outcomes by coordinating care, providing psychosocial support, making appropriate referrals, and providing and reinforcing patient education.

The contact information for the Cancer Patient Navigators can be found on the *Cancer Care Nova Scotia* website, or by phoning 1-866-524-1234. Currently (2015), there is no Cancer Patient Navigator in the Central Zone of the Nova Scotia Health Authority.

- All suspected lung cancer patients should be referred to their local Cancer Patient Navigator, or a designated health care provider who can provide navigation functions, at the time of diagnosis.
- If patients decline referral to a Cancer Patient Navigator at the time of diagnosis, it should be offered again periodically or patients should be made aware that they may self-refer at anytime.

# **Screening for Distress**

Screening for distress, which is the routine and systematic approach to quickly identifying psychosocial health care needs, helps to identify patients who are at risk of psychological, physical or social distress. This screening provides the opportunity for further assessment that is specific to the patient's needs and recognizes the individual factors that may place them at increased risk of distress. A detailed assessment helps to identify those patients who require more specific one-to-one intervention and and/or referral to a psychosocial oncology specialist. In Nova Scotia, there are three components to the distress screening tool: The Edmonton Symptom Assessment System (ESAS), The Canadian Problem Checklist (CPC), and the Distress Thermometer (DT). These tools are a quick way to help identify distress related issues. Refer to the CCNS Best Practice Guideline for the Management of Cancer-Related Distress in Adults for more details. 38

- All lung cancer patients should be offered screening for and management of distress shortly
  after diagnosis and again at critical transition times (e.g. the start and end of cancer treatment,
  disease progression).
- Screening for distress may be performed by the Cancer Patient Navigator, cancer centre staff, or primary care provider, wherever the patient is seen first. <sup>38</sup>
- If patients decline to complete the distress screening tool, it should be offered again as outlined in the CCNS Best Practice Guidelines for the Management of Cancer-Related Distress in Adults.

# **Referral to Other Health Care Providers**

 Health care providers should inform patients of the roles and benefits of other health care providers and make referrals as necessary (e.g. other specialist physicians, social work, dietician, palliative care consultation team).<sup>5</sup>

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# **Section VII: Additional Imaging for Staging**

# A. PET

# Refer for PET for diagnosis:

- For nodules with a solid component of at least 8mm, if contemplating curative therapy, PET should be performed prior to definitive treatment.<sup>6,24,27</sup>
  - NOTE: For high risk patients with high risk nodule(s) on CT, do breath-hold CT as part of PET for diagnosis if using to replace pre-surgical biopsy.
  - NOTE: For low risk patients with a low risk solid nodule, PET can be used to prevent surgery.
  - NOTE: Possibly transient nodules either based on CT or clinical features need follow up CT before going to PET as active inflammation may result in false positive PET.
  - o NOTE: Nova Scotia does not have a high incidence of granulomatous disease; therefore these PET recommendations may differ from guidelines of other jurisdictions.

# Refer for PET for staging:

- Treatment for cure<sup>4,17,39</sup>
- Small cell lung cancer limited stage (urgent)<sup>40</sup>
- Radiation therapy planning (as decided by radiation oncologist)
- Suspected metastatic lesions
- Multiple lung lesions
- Previous cancer (except non-melanoma skin cancer)

# Do not refer for PET:

- a) High likelihood of false negative results:
  - Pure ground glass opacities<sup>17</sup>
  - Any nodule without solid component of at least 8mm
    - NOTE: \*Exception in rare situations of multiple persistent mixed density nodules, PET may help plan surgery (help decide which nodule to resect)
- b) High likelihood of false positive results:
  - Possible transient nodules either based on CT or clinical features do not do PET until persistence is proven on CT (6 weeks).
- c) Unlikely to impact treatment:
  - Any patient not being treated for cure (except for radiation planning where indicated by radiation oncologist)
  - Advanced cancer
  - Palliative cases

# **Ordering physicians for PET:**

• Specialist physicians managing cancer (respirologist, surgeon, oncologists, radiologists)

# **Timing of PET:**

- Tissue confirmation is not required to order PET; however, the timing of needle biopsy needs to be considered.
  - o If needle biopsy is contemplated, it should be scheduled after the PET if possible.
  - o If PET is done post-biopsy, a one month wait is recommended to allow inflammation to subside to avoid false positive results.
- A patient who has a complicating pneumonia should have a PET scan delayed until 10 days after the conclusion of the satisfactory antibiotic treatment regime if possible.
- Patients traveling a distance from outside of Halifax (e.g. 2 hours or more) will be eligible for coordinated same day PET and specialist appointments.

# **Reporting timeline for PET:**

• 24 hours (shorter for same day PET requests)

#### **PET report requirements:**

 Radiologists reporting PET should look at the previous CT and report on gross change in nodule size.

#### B. Bone Scan

# Refer for bone scan:

- Patient suspicious for bone metastasis and <u>not</u> being treated for potential cure (i.e. patient will not have a PET scan).<sup>38</sup>
- Lung cancer patients with high ALK phosphatase if PET can't be done or there is continued clinical concern for bone metastasis following a PET and clinical management will be affected.
- Patient unable to travel to Halifax for PET. 38
- Negative PET with high clinical suspicion of bone metastasis in the skull or long bones.<sup>41</sup>

#### Do not refer for bone scan:

- Bone scan is not needed when PET has been done (e.g. potential curative cases). 6,41
  - o NOTE: \*Exception- patients who have had a PET scan which has not shown lesions but there is a high clinical suspicion of bone metastasis in the skull or long bones.<sup>41</sup>

# C. Brain Imaging

#### Refer for brain imaging:

- MRI of the brain without and with contrast should be ordered at the first specialist appointment if indicated. This test should be cancelled if not needed (e.g. other test results available in the meantime).
- In patients with suspected lung cancer, neurological symptoms and a brain lesion suspected based on unenhanced CT head, an MRI of the brain without and with contrast should be performed within 24 hours of onset of neurological symptoms.<sup>6</sup>

- O In the absence of timely available MRI, a CT head without and with contrast enhancement should be performed within 24 hours of onset of neurological symptoms. CT head alone should not be used to rule out brain metastasis; however, it can be used as a first test to help triage patients with neurological symptoms and negative CT head results for an urgent MRI of the brain without and with contrast.
- In patients with suspected or known lung cancer beyond clinical Stage I, with no neurologic symptoms, and where curative treatment is a possibility, an urgent MRI of the brain without and with contrast should be used to rule out brain metastases.<sup>17</sup>
  - IV contrast enhanced MRI is more sensitive than CT for the detection of brain metastases.
- In patients with a solitary brain mass, other primary cancers, including lung cancer, should be ruled out.
- Patients who will receive concurrent chemoradiotherapy should have an MRI of the brain without and with contrast at the discretion of the medical and/or radiation oncologist, and should be triaged as urgent in cases where treatment will be starting immediately.
- Small cell lung cancer patients who are a candidate for prophylactic cranial irradiation.

# MRI head protocol for lung cancer patients:

MRI of the brain without and with contrast

# Do not refer for MRI brain imaging:

- Clinical stage I operable lung cancer patients without neurological symptoms.
- Palliative patients who do not have neurological symptoms and who are not candidates for treatment of brain metastases.
- Patients who will have palliative whole brain radiation (except for radiation planning where indicated by radiation oncologist).

# D. Other Staging Imaging

# Refer for MRI chest:

Possible chest wall or mediastinal invasion, where it will inform treatment decision making.<sup>6</sup>

NOTE: This test is usually performed when recommended by a radiologist or specialist.

# Refer for additional CT imaging:

• Repeat enhanced\* chest CT and upper abdomen needed if previous is outdated (e.g. older than 3 months).<sup>6</sup>

NOTE: For patients with contrast allergies or high risk of contrast induced nephropathy an unenhanced CT is often sufficient. However, the liver cannot be staged on an unenhanced exam and may require US.

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# **Section VIII: Treatment Referral**

These recommendations are not inclusive of oncologic emergencies (e.g. superior vena cava obstruction, suspected spinal cord compression). Refer to Guidelines for the Management of Oncologic Emergencies in Adult Cancer Patients for management protocols.

# A. Decisions Based on Stage Information

#### **Decisions based on stage information:**

- When staging investigations are complete, the most responsible health care provider will inform the patient of the stage of their disease and outline treatment options.
- The treatment options provided should take into account patient age, weight loss, comorbidities, life expectancy, disease stage, performance status (ECOG) and expressed preferences.
- Based on the patient's choices, refer as appropriate.
- Patients should be referred to the appropriate specialist(s) without delay.

### **B.** Treatment Referral

#### **Referral to Treating Specialist**

Referrals to medical and radiation oncology (including satellite clinics) should be sent to the Nova Scotia Cancer Centre (all Zones except Eastern) or the Cape Breton Cancer Centre (Eastern Zone). Thoracic surgery referrals should be sent to thoracic surgery at the QEII.

Histologic confirmation of lung cancer is normally required for referral to medical or radiation oncology. However, the following patients may be referred to medical/radiation oncology for opinion before histologic confirmation of lung cancer:

- Clinically suspected small cell lung cancer
- Highly symptomatic patients
  - o e.g. pain from bone metastasis
- Patients where attempts at tissue diagnosis have failed

Non-curative patients should be referred to medical and/or radiation oncology for consultation as appropriate as well as to their local palliative care team for consultative support in managing complex symptoms and/or unmet needs.

Referring and treating physicians should ensure that patients understand the purpose of their treatment plan (e.g. curative vs. palliative intent).

# **Referrals to Thoracic Cancer Site Team:**

• For complex or difficult cases where treatment options are unclear, refer to multidisciplinary assessment clinic and/or Thoracic Cancer Site Team for discussion and recommendations.

- Patients who will receive concurrent chemoradiotherapy should be discussed, when possible, by the Thoracic Cancer Site Team.<sup>4</sup>
- Diagnosis should be confirmed prior to submission of case to Thoracic Cancer Site Team.
- Any treating specialist in Nova Scotia may submit a case for discussion.

# Timeline for treating specialist consult appointment:

- Thoracic surgeon
  - o 1 week from date of receipt of referral
- Medical/radiation oncology:
  - o 1 week from date of receipt of referral for small cell lung cancer<sup>4,42</sup>
  - 2 weeks from date of receipt of referral for all other lung cancers<sup>42</sup>

# **Supportive Care Referrals:**

- At the time of referral to treating specialist, all lung cancer patients should also be referred to their local Cancer Patient Navigator, if not already done.
- All lung cancer patients should be offered screening for and management of distress at time of referral to cancer centre, if not already performed.

# C. Target Timelines for Treatment Initiation

# **Target timelines:**

- From first presentation with symptoms suggestive of lung cancer to initiation of treatment
  - Target timeline= 60 days
- From treating specialist consult (thoracic surgeon, medical oncologist, radiation oncologist) to initiation of treatment
  - o Target timeline= 1 month from receipt of consult

# Special considerations for shorter timelines:

- Patients receiving chemoradiotherapy for cure
- Highly symptomatic lung cancer
- Small cell lung cancer

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**Appendix A: Clinically Detected Lung Cancer Working Group Members** 

def Care for Cancer, Nova Scotia Health Authority; Clinical Head, Cancer Program, Halifax  Lisa Aikens (since Feb 2015) Patient Advisor, Stellarton  Robert Berry (Corresponding) Interventional Radiologist, Halifax  David Bowes Radiation Oncologist, Nova Scotia Cancer Centre, Halifax  Matthew Boyd Respirologist, Antigonish  Peter Bromley Radiologist, Kentville  Meredith Chiasson Respirologist, Halifax  Susan Clarke-Tizzard (since Feb 2015) Patient Advisor, Sussex, NB  Daniel Du Toit Internal Medicine, Bridgewater  Michael Dunn (Corresponding) Department Head, Diagnostic Imaging, Kentville  Islam Eissa (since June 2015) Internal Medicine, Yarmouth  Jens Heidenreich (Corresponding) Neuroradiologist, Halifax  Kian Khodadad (since Dec 2014) Medical Oncologist, Cape Breton Cancer Centre, Sydney  Ashraf Mahmoud-Ahmed (Corresponding since Dec 2014) Radiation Oncologist, Cape Breton Cancer Centre, Sydney  Ashraf Mahmoud-Ahmed (Corresponding) General Surgeon, Sydney  Harsh Mishra Family Physician, Halifax  Aneil Mujoomdar (Corresponding) Thoracic Surgeon, Halifax  Aneil Mujoomdar (Corresponding) Thoracic Surgeon, Halifax  Leah Nolan Referral Officer, Nova Scotia Cancer Centre, Halifax  Jill Petrella Manager, Quality and Cancer Site Teams, CCNS  Andrew Ross (Corresponding) Nuclear Medicine Radiologist, PET, Halifax  Joel Surette Radiologist, Cape Breton Cancer Centre, Sydney  Christy Thurber Cancer Standards Development Officer, CCNS  Sandra Wajstaub (since Dec 2014) Radiation Oncologist, Cape Breton Cancer Centre, Sydney	Member	Role/Location
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Darolyn Walker Cancer Patient Navigator, Yarmouth	Christy Thurber	Cancer Standards Development Officer, CCNS
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	Darolyn Walker	Cancer Patient Navigator, Yarmouth
Zhaolin Xu Pathologist, Halifax	Zhaolin Xu	Pathologist, Halifax

# **Appendix B: Guideline Development and External Review Process**

#### **Purpose**

Lung cancer is the leading cause of cancer death in Nova Scotia and, despite advances in treatment, there has been little improvement in survival. Local anecdotal and quantitative evidence showed less than optimal wait times and system inefficiencies. There was concern that early stage disease would advance while patients were experiencing delays in the diagnostic process, resulting in poorer prognoses. Added to this, in April 2015, thoracic surgery services, a common diagnostic and treatment modality for lung cancer, became centralized in Halifax. This was expected to particularly affect the organization and delivery of care for lung cancer patients in Eastern Nova Scotia. These reasons provided the opportunity to review and improve the current process for the diagnosis and referral of suspected lung cancer.

Throughout Canada, the feasibility of organized lung cancer screening for high risk populations is currently being explored. The introduction of an organized screening program would require an efficient diagnostic pathway for both screen detected and symptomatic lung cancer patients.

# Working Group Membership

The guideline development process began in September 2014 following the establishment of the Clinically Detected Lung Cancer Working Group. The Working Group consisted of representatives from key health disciplines from across the province. Although it was Cancer Care Nova Scotia's (CCNS) aim to have Patient Advisors as members of the Working Group from the outset, this goal was not realized until February 2015 due to lack of response to the call. The full list of Working Group members can be found in Appendix A.

All but three members of the Working Group completed Conflict of Interest Disclosure Declarations. A summary of declared conflicts is provided below and was shared with the Working Group to allow for transparent management of conflicts.

Dr. Bethune	Advisory board Pfizer
	<ul> <li>Administrative Coordinator Atlantic Canada Molecular Oncology Center</li> </ul>
Dr. Manos	Incorporated medical practice
	<ul> <li>Involved in Pan Canadian Early Detection of Lung Cancer</li> </ul>
	<ul> <li>Member of CPAC Working Group on Lung Cancer Screening</li> </ul>
	<ul> <li>Research grant from Lung Association of Nova Scotia</li> </ul>
	<ul> <li>Published commentary in "Oncology Exchange Journal", "CT Screening for</li> </ul>
	Lung Cancer: Controversy and Misconceptions"
Ms. Nolan	Data entry for ER/PR HER2 research
Dr. Xu	CPAC Lung Cancer Screening Working Group Chair

#### Guideline Development

The Working Group scope was from initial presentation/suspicion of lung cancer to definitive diagnosis/decision to treat. Prevention and treatment recommendations were out of scope.

The Working Group met regularly from September 2014 to September 2015.

It was decided by the Working Group not to adopt an existing lung cancer pathway, but to develop recommendations tailored for Nova Scotia based on existing background documents and issues identified by patients and families using an adaptation approach. This proven approach identifies recent, well-developed, evidence-based documents from other jurisdictions and then adapts them for the local jurisdiction rather than starting "de novo" with primary literature. Starting with an environmental scan of Canadian lung cancer pathways conducted by the Canadian Association of Provincial Cancer Agencies (CAPCA) and the Canadian Partnership Against Cancer (CPAC), CCNS staff reviewed the websites of all Canadian cancer agencies and other credible English-language guideline development organizations for current relevant guidelines. After review of all identified pathways and guidelines, the main sources for this document were the lung cancer pathways developed by Cancer Care Ontario (including supporting documents) and Cancer Care Manitoba. Other source documents included lung cancer guidelines from the National Institute for Health and Clinical Excellence (NICE) (UK), Scottish Intercollegiate Guidelines Network (SIGN), and the American College of Chest Physicians (ACCP).

These were supplemented by results from a CCNS lung cancer patient and family focus group in July 2014, as well as a chart review and case study from the QEII to give the Working Group a current description of the journey for lung cancer patients and families in Nova Scotia.

The guideline document does not include rationale or a synthesis of evidence but provides references to the source documentation. A full list of references used can be found at the end of the document.

To make the best use of Working Group members' time, the meeting schedule was organized by topic (e.g. Presentation; Radiology; Biopsy and Molecular Testing) so that individuals who were not particularly involved or interested in that topic area would not have to attend. Where specific expertise was required, other health care providers were invited to the meetings (e.g. PET, brain imaging). Draft recommendations based on the source documents were reviewed, discussed within the Nova Scotia context and revised as necessary. Where additional information was required, further research was performed.

# **External Review Process**

An external review of the draft guidelines was conducted throughout May and June, 2015. This review provided the opportunity for Nova Scotia health care providers, administrators and lung cancer patients, survivors and their families, friends and caregivers to give feedback on the validity and appropriateness of the draft guidelines.

#### Methods

The three groups of stakeholders were asked to review and comment on the draft guidelines by electronic survey. The survey was divided into sections so respondents could focus on their area of expertise/interest; however, all respondents were able to review the entire draft document and comment on any section.

# Health care provider and administrator survey

Health care providers and administrators received the draft document and survey link through the Nova Scotia Health Authority Vice Presidents, Zone Medical Executive Directors, Zone Operations Executive Directors, Senior Director Laboratory and Diagnostic Services, and the Executive Director of Acute & Tertiary Care and Executive Director Primary Health Care & Emergency Health Services at the Nova Scotia Department of Health and Wellness. Communications were also sent out to health care providers through Doctors Nova Scotia, Nova Scotia College of Family Physicians, College of Registered Nurses of Nova Scotia, Nova Scotia Association of Nurse Practitioners, Family Practice Nurses Association of Nova Scotia and through relevant CCNS' working groups. Primary care providers who volunteered for the external review at the Spring Oncology Workshop in April 2014, health care providers who were previously engaged in developing specific sections of the guidelines, and the Thoracic Cancer Site Team were also contacted directly. There were 23 individual and 6 group surveys completed, as well as 9 individual and 5 group emailed responses received with good representation from relevant health disciplines and Nova Scotia Health Authority zones. Further feedback was sought from experts in the fields of palliative and supportive care due to the lack of response from those areas.

Several health care providers outside of the Working Group were engaged in the development of the draft guidelines, such as respirologists, radiologists, and pathologists. The number of responses to the external review does not reflect the extent of the input received from these groups.

# Public survey

The public survey was circulated to the CCNS Cancer Patient Family Network, Canadian Cancer Society-Nova Scotia Division, Lung Cancer Canada, Lung Association of Nova Scotia, Health Association of African Canadians, as well as advertised on CCNS' social media and website. A press release was released, resulting in three radio interviews. The public was given the opportunity to complete an electronic survey or participate in a focus group. The focus groups were replaced with phone interviews due to the low number of participants. There were 13 complete and 5 incomplete survey responses as well as 3 phone interviews completed with representation from around the province.

#### Results

The survey responses were collated by CCNS and shared with the Working Group. The majority of responses were positive and supportive of the draft guidelines. Some respondents provided positive feedback through written comments, such as "Very good document, the group has thought of everything during the patient journey" and "Great to see this list of recommendations- much needed."

The feedback was reviewed by the Working Group and recommendations were revised as appropriate. The written feedback comments and the Working Group's corresponding responses and/or actions were recorded for accountability purposes.

The Working Group approved the guidelines in November 2015. The guideline development process was endorsed by the CCNS Clinical Standards Oversight Committee and Chris Collier, Interim Chief Operating Officer, CCNS in December 2015. The guidelines were then submitted through the final approval

process. The guidelines will be reviewed three years after approval or revised as new evidence becomes available.

#### Cancer Care Nova Scotia Involvement

As the provincial cancer agency for Nova Scotia, the mandate for Cancer Care Nova Scotia (CCNS) includes the development of provincial standards and guidelines related to cancer care and treatment. CCNS staff worked with the Working Group members to develop the guidelines by providing meeting facilitation support, organization for the Working Group meetings including all communication with Working Group members and logistical arrangements. CCNS staff also coordinated the writing and editing of the various drafts. The views and interests of CCNS did not influence the decision-making.

To facilitate the involvement of Working Group members, CCNS removed financial barriers by providing travel or distance technology for those participating from outside Halifax, and reimbursing fee for service physicians for their time during the meetings (at the approved Department of Health and Wellness rate for administrative work).

CCNS will fund the design, printing and dissemination of the guideline document as well as work with stakeholders in implementing the recommendations.