Evidence-Based Series 26-3

A Quality Initiative of the Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Follow-up and Surveillance of Curatively Treated Lung Cancer Patients

Y.C. Ung, L.H. Souter, G. Darling, J. Dobranowski, L. Donohue, N. Leighl, P.M. Ellis and the Lung Cancer Follow-up Expert Panel

Report Date: August 29, 2014

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https://www.cancercare.on.ca/toolbox/qualityguidelines/clin-program/survivorship/

Section 1: Guideline Recommendations
Section 2: Evidentiary Base
Section 3: Development Methods, Recommendations Development and External Review Process

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Follow-up and Surveillance of Curatively Treated Lung Cancer Patients

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Evidence-Based Series 26-3: Section 1

A Quality Initiative of the
Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Follow-up and Surveillance of Curatively Treated
Lung Cancer Patients:
Guideline Recommendations

Y.C. Ung, L.H. Souter, G. Darling, J. Dobranowski, L. Donohue, N. Leighl, P.M. Ellis and the
Lung Cancer Follow-up Expert Panel

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GUIDELINE OBJECTIVES
The primary objective of this guideline is to develop recommendations for optimal
clinical and imaging surveillance and disease control after curative-intent treatment for lung
cancer. In addition, the guideline includes an assessment of late toxicity from cancer
treatments, quality of life of lung cancer survivors and the benefit of smoking cessation
interventions.

TARGET POPULATION
Studies of both small cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC)
patients after curative-intent treatment were considered.

INTENDED USERS
This guideline is targeted to thoracic surgeons, medical and radiation oncologists
specializing in lung cancer, radiologists, family physicians, respirologists, nurses and
psychosocial care providers.

RECOMMENDATIONS, KEY EVIDENCE, AND JUSTIFICATION

Table 1 summarizes the recommended evaluations and intervals for the routine
surveillance of NSCLC and SCLC survivors. These recommendations are based on the
expert opinion of the authors, interpretation of the available evidence, and feedback
obtained from health care professionals across Ontario through an extensive review
process (described in Section 3 of this document). There is currently no data
demonstrating improvements in survival from routine surveillance. There are however
clinical options for managing local or locoregional recurrence. Therefore, routine
surveillance schedules have been designed in order to detect local or locoregional
recurrence and new primary lung cancers that are amenable to salvage therapy in
asymptomatic patients during follow-up care. Survivors who develop symptoms
suggestive of recurrence, should be evaluated according to those symptoms.
**RECOMMENDATION 1**

Following curative-intent treatment for NSCLC, survivors should receive scheduled follow-up visits that include a medical history, physical examination and chest imaging. Clinical evaluations should be conducted every three months in years 1 and 2, every six months in year 3 and annually thereafter.

**Summary of Key Evidence for Recommendation 1**

One systematic review with meta-analysis found no survival benefit with a more intense follow-up schedule for NSCLC survivors (hazard ratio [HR], 0.83; 95% confidence interval [CI], 0.66-1.05; p=0.13) (1). However, asymptomatic recurrence detection was associated with a longer survival time (HR, 0.61; 95%CI, 0.50-0.74; p<0.01) (1). Other research has determined that in both NSCLC and SCLC, the majority of recurrences are diagnosed in the first two years (2).

A systematic review that evaluated the role of computed tomography (CT) follow-up one year after lobectomy did not find a clear survival benefit for CT scans (3). However, a more recent study points to a role for minimal-dose CT (MnDCT) scans, which showed higher sensitivity (94.2% vs. 21.2%; p<0.0001) and negative predictive value (99.7% vs. 96.2%; p=0.007) than chest x-ray for detecting new primary tumours and recurrent lung cancer at an early stage (4).

**Justification for Recommendation 1**

There is very little high level evidence to inform this recommendation. NSCLC survivors should be followed after curative-intent treatment in order to detect local or locoregional recurrence and new primary lung cancers, which are amenable to resection or radical radiation therapy for salvage. For this reason, the Working Group valued overall survival rate over recurrence detection rate. Visits should include medical history with attention to new symptoms in the aerodigestive tract, physical examination and chest imaging. Due to the lack of evidence to inform which frequency is most appropriate, a consensus approach was used to make a recommendation on the appropriate timing of follow-up evaluations in the expert opinion of the Working Group. The consensus process incorporated the evidence that most recurrences are detected in the first two years following curative treatment (2), the indication that asymptomatic recurrence detection is associated with longer survival (1) and the clinical experience of the Working Group members. Additionally, even though data for surveillance beyond five years is limited, the Working Group feels confident in recommending ongoing annual surveillance after year five as this population of patients remains at a heightened risk of developing new lung cancers. Data from the National Lung Screening Trial (5,6) for screening high risk populations for lung cancer recommended low dose CT scans to reduce mortality rates from lung cancer.

Due to the limited evidence, there is no clear indication of the most appropriate chest imaging modality for surveillance. However, based on the limited evidence and expert opinion, Qualifying Statements with imaging modality suggestions have been included for NSCLC survivors. Although there is no clear evidence from studies focusing on recurrence rate detection, the clinical standard among Ontario health care professionals is CT scan, with the appropriate dose and use of contrast IV remaining controversial. Due to radiation dose concerns when performing CT scans for surveillance, lower dose CT scan protocols are of great interest. The best evidence for the value of low-dose CT (LDCT) surveillance comes from the National Lung Screening Trial (5,6), which indicated that LDCT was better than chest radiography in detecting early-stage lung cancers. The Working Group concluded that the cohort study that demonstrated the superiority of MnDCT over chest x-ray for follow-up of NSCLC survivors (4) paired with the success of LDCT in screening (5,6) provide rationale to
suggest either LDCT or MnDCT rather than chest x-ray in follow-up care of NSCLC survivors. The suggestion to include chest CT as a reasonable option for appropriate surveillance imaging of NSCLC survivors is in agreement with recommendations published by the American Association for Thoracic Surgery (AATS) (7), the American College of Chest Physicians (ACCP) (8), the European Society for Medical Oncology (ESMO) (9) and the National Comprehensive Cancer Network (NCCN) (10).

Qualifying Statements for Recommendation 1 (Table 1)
Selection of an appropriate imaging modality should reflect the competing risk of locoregional recurrence, which is potentially curative versus distant recurrence, which is not curative. A cohort study (4) and the National Lung Screening Trial (5,6) indicated that MnDCT and LDCT detect pulmonary lesions better than chest x-ray, yet no demonstrated survival benefit has been established in patients treated by surgical resection with curative intent. Thus, for routine surveillance, LDCT or MnDCT without IV contrast may be a reasonable option instead of chest x-ray. The MnDCT cohort study conducted chest CTs at three months post-treatment, followed by six months post-treatment, then at six month intervals until the end of year 2, followed by annually until year 5. As this is the best available schedule at this time, the intervals are considered reasonable, with the addition of annual surveillance exceeding year 5, as outlined in the Justification section. Even though surveillance is recommended annually until end of life, health care professionals should use their own discretion in determining the applicability of annual surveillance in patients who are not well enough to undergo treatment if a new cancer is detected. When recurrent disease or new disease is suspected, either from constitutional symptoms or chest imaging findings, diagnostic chest CT plus upper abdomen CT scan is suggested to identify local recurrence or a new lung primary.

RECOMMENDATION 2
Following curative-intent treatment for SCLC, survivors should receive scheduled follow-up visits that include a medical history, physical examination and chest imaging. Clinical evaluations should be conducted every three months in years 1 and 2, every six months in year 3 and annually thereafter.

Summary of Key Evidence for Recommendation 2
One systematic review with meta-analysis found no survival benefit with a more intense follow-up schedule for SCLC survivors (1). Other research has determined that in both NSCLC and SCLC, the majority of recurrences are diagnosed in the first two years (2).

Justification for Recommendation 2
There was very little high level evidence to inform this recommendation. SCLC survivors should be followed after curative treatment in order to detect new primary lung cancers and local recurrences that may be amenable to further curative treatment. For this reason, follow-up schedules that result in a high detection rate for recurrence are only of value if this translates into an increase in overall survival. Thus, overall survival rate is valued over recurrence detection rate by the Working Group. Visits should include medical history with attention to new symptoms in the aerodigestive tract, physical examination and chest imaging. A consensus approach was used to determine the appropriate timing of follow-up evaluations in the expert opinion of the Working Group. The consensus process incorporated both the evidence that most recurrences are detected in the first two years following curative treatment (2) and that more intense follow-up schedules do not result in a
longer overall survival time (1), as well as incorporating the clinical experience of the Working Group members.

Due to a lack of evidence, there is no clear indication in the literature on the appropriate surveillance imaging modality for SCLC survivors. The clinical standard among Ontarian oncologists is to perform a CT scan, but there is no evidence to support this choice in a lung cancer survivor population. Based on extrapolation from screening data and expert opinion, Qualifying Statements with imaging modality suggestions have been included for SCLC survivors. Data from the National Lung Screening Trial (5,6) indicated that LDCT was better than radiography in detecting early-stage lung cancers. Based on the superiority of CT to chest x-ray for screening in a high-risk population, in the expert opinion of the Working Group, surveillance of SCLC survivors with CT scans for detection of recurrence or progression may be a reasonable option. Since this suggestion is based on expert opinion and interpretation of data from a screening population, and not the target population of the guideline, a specific radiation dose cannot be included. The suggestion to include chest CT as a reasonable option for appropriate surveillance imaging of SCLC survivors is in agreement with the ESMO guideline for SCLC patients, which states that survivors should be followed with CT scans (11).

Qualifying Statements for Recommendation 2 (Table 1)

Selection of an appropriate imaging modality should reflect the competing risk of locoregional recurrence, which is potentially curative versus distant recurrence, which is not curative. Based on the clinical experience of the Working Group and results from the National Lung Screening Trial (5,6), for routine surveillance, diagnostic CT without IV contrast is preferable to chest x-ray for detection of pulmonary lesions, though no survival benefit has been established. Also based on the clinical experience of the Working Group, diagnostic CT with contrast is suggested for detection of recurrence in mediastinal lymph nodes. In the expert opinion of the Working Group, CT imaging may be conducted three months post-treatment, followed by six months post-treatment, then at six month intervals until the end of year 2, followed by annually thereafter. Beyond year 2, LDCT or MnDCT could be considered rather than a diagnostic CT. Even though surveillance is recommended annually until end of life, health care professionals should use their own discretion in determining the applicability of annual surveillance in patients who are not well enough to undergo treatment if a new cancer is detected. When recurrent disease or new disease is suspected, either from constitutional symptoms or chest imaging findings, diagnostic chest CT plus upper abdomen CT scan is suggested to identify local recurrence or a new lung primary.
Table 1. Evaluations and intervals for routine surveillance of lung cancer survivors after curative-intent therapy.

<table>
<thead>
<tr>
<th></th>
<th>NSCLC</th>
<th>SCLC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical visit evaluations</td>
<td>Medical history, physical exam and chest imaging</td>
<td>Medical history, physical exam and chest imaging</td>
</tr>
<tr>
<td>Clinical visit frequency</td>
<td>Years 1-2: every 3 months</td>
<td>Years 1-2: every 3 months</td>
</tr>
<tr>
<td></td>
<td>Year 3: every 6 months</td>
<td>Year 3: every 6 months</td>
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<tr>
<td></td>
<td>Years 4+: annually</td>
<td>Years 4+: annually</td>
</tr>
<tr>
<td>Medical imaging modality</td>
<td>LDCT(^{\text{a}}) or MnDCT(^{\text{b}}) without contrast may be a reasonable option over chest x-ray for detection of pulmonary lesions</td>
<td>Diagnostic CT without contrast may be a reasonable option over chest x-ray for detection of pulmonary lesions(^{\text{ii}})</td>
</tr>
<tr>
<td></td>
<td>Diagnosing CT with contrast is suggested to detect recurrence in mediastinal lymph nodes(^{\text{i}})</td>
<td></td>
</tr>
<tr>
<td>Surveillance imaging frequency</td>
<td>Year 1: 3, 6 and 12 months post-treatment</td>
<td>Year 1: 3, 6 and 12 months post-treatment</td>
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<tr>
<td></td>
<td>Year 2: every 6 months (18 and 24 months post-treatment)</td>
<td>Year 2: every 6 months (18 and 24 months post-treatment)</td>
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<tr>
<td></td>
<td>Years 3+: annually</td>
<td>Years 3+: annually</td>
</tr>
<tr>
<td>Medical imaging when recurrent disease or new disease is suspected</td>
<td>Diagnostic chest CT with contrast plus upper abdomen scan is suggested to detect local recurrence or new primary lung cancer(^{\text{i}})</td>
<td>Diagnostic chest CT with contrast plus upper abdomen scan is suggested to detect local recurrence or new primary lung cancer(^{\text{i}})</td>
</tr>
<tr>
<td></td>
<td>If patient is symptomatic, imaging modality specific to patient’s symptoms is recommended(^{\text{i}})</td>
<td>If patient is symptomatic, imaging modality specific to patient’s symptoms is recommended(^{\text{i}})</td>
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\(^{\text{i}}\) Based on consensus of expert opinion.  
\(^{\text{ii}}\) Based on extrapolation data from the National Lung Screening Trial (5,6).  
\(^{\text{iii}}\) Based on a MnDCT vs. chest x-ray cohort study (4).  

Abbreviations: LDCT, low-dose computed tomography; MnDCT, minimal-dose computed tomography; NSCLC, non-small cell lung cancer; SCLC, small cell lung cancer.

**RECOMMENDATION 3**

For both NSCLC and SCLC survivors, no recommendation can be made in relation to positron emission tomography (PET)/CT.

**Summary of Key Evidence for Recommendation 3**

The only identified studies that assessed PET/CT surveillance of lung cancer survivors were in NSCLC survivor populations. Two PET/CT diagnostic studies indicated a benefit for PET/CT over CT alone for recurrence detection (12,13), while another demonstrated a benefit for PET/CT over non-contrast CT for detection of extrathoracic and mediastinal metastases (14). One study, looking at the ability to detect local recurrence, found that almost 26% of the recurrences diagnosed by PET/CT were recurrences within the ipsilateral lung (12). In another diagnostic study, PET/CT scanning led to the detection of lung cancer recurrence that was amenable to salvage therapy in a small proportion (3% of total) of the patients enrolled (13).
Justification for Recommendation 3

The Working Group was unable to provide a recommendation for PET/CT surveillance of NSCLC and SCLC survivors based on the identified evidence. Diagnostic studies have shown better sensitivity, specificity and accuracy of PET/CT compared with CT alone and point to a role for PET/CT in diagnosing local and locoregional recurrences, which may be amenable to salvage therapy (12, 13). However, due to the low percentage of local recurrence detected by PET/CT in these studies and the higher doses of radiation patients would receive with PET/CT compared with CT alone, the Working Group feels that the evidence does not point to a clinically important difference in patient outcomes with PET/CT and the data are not strong enough upon which to base a recommendation.

RECOMMENDATION 4

In the expert opinion of the authors, any new and persistent or worsening symptom warrants the consideration of a recurrence, especially:

Constitutional symptoms:
- Dysphagia
- Fatigue (new onset)
- Nausea or vomiting (unexplained)
- New finger clubbing
- Suspicious lymphadenopathy
- Sweats (unexplained)
- Thrombosis
- Weight loss or loss of appetite

Pain:
- Bone pain
- Chest pain
- Caveat shoulder pain not related to trauma

Neurological symptoms:
- Headaches (if persistent)
- New neurological signs suggestive of brain metastasis or cord compression such as leg weakness or speech changes
- Headache or focal neurological symptoms

Respiratory symptoms:
- Cough (despite use of antibiotics)
- Dyspnea
- Hemoptysis
- Hoarseness
- Signs of superior vena cava obstruction
- Stridor

Summary of Key Evidence for Recommendation 4

Only one prospective cohort study was identified to inform this recommendation. This PET/CT diagnostic study recorded the symptoms experienced by patients who had developed
progressive disease and found that these patients experienced more pain and neurological issues than did those without progressive disease (13).

Justification for Recommendation 4
The included study enrolled a modest sample size of 100 patients, with only 24 patients developing progressive disease (13). Due to the lack of evidence and small sample size of the included study, the Working Group decided to use expert opinion in a consensus process to list the potential symptoms of recurrence.

RECOMMENDATION 5
Health-related quality of life (QoL) is very important for long-term survivors suffering from late side effects of their curative-intent therapy (including surgery, chemotherapy and radiation therapy). The following is a summary of issues reported by survivors. Health care professionals need to aid lung cancer survivors in handling these symptoms to improve QoL.

Constitutional Issues:
- Anxiety
- Cough
- Decline in appetite
- Decrease in general health
- Depression
- Dysphagia
- Esophageal stricture
- Fatigue
- Pain
- Physical ability restrictions
- Reduced sleep quality
- Shortness of breath

Long-Term Chemotherapy Effects:
- Hearing loss
- Neuropathies
- Renal impairment

Long-Term Radiation Effects:
- Breathing complications
- Breathlessness/Dyspnea

Long-Term Surgery Effects:
- Empyema
- Oxygen dependence
- Post-thoracotomy pain syndrome
- Reduced exercise tolerance or activity limitations
- Shortness of breath

Summary of Key Evidence for Recommendation 5
When overall QoL profiles of lung cancer survivors were analyzed, it was found that survivors of both NSCLC and SCLC experienced a reduction in the physical domains of the QoL.

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questionnaires for up to one year post surgery (15,16). There was an increase in the QoL mental domain level above that experienced pre-surgery by two years, but this level was still lower than an age-matched reference population (16). When only NSCLC survivors were followed after lobectomy, 66% of survivors experienced improved or stable QoL scores, while 71% of survivors experienced improved or stable scores following pneumonectomy or bilobectomy (17).

A systematic review that assessed the specific treatment-related long-term effects found that survivors of lung cancer report physical ability restrictions, depression, decreases in general health and vitality, and increased body pain (2). Prospective cohort studies evaluating non-recurrence related issues found that lung cancer survivors experienced long-term dyspnea (18-20), cough (18,20), fatigue (18,20), impaired breathing (21), increased pain (20,21), decline in appetite (20,21) and reduced sleep efficiency (19). Studies that focused solely on survivors of NSCLC found that a majority of these survivors experienced some degree of pneumonitis (22) and a sustained decrease in multiple QoL domains (23).

Justification for Recommendation 5
The literature search on this question was designed to assess both the QoL and treatment-related symptom burden of lung cancer survivors, which quite often go hand-in-hand. The studies that informed the research question ranged from systematic reviews and randomized controlled trials (RCTs) to non-randomized prospective cohort studies. All the included studies used prospective data collection and analyzed the study population through comparisons either between groups or within the study group, across time. Unfortunately, since all non-randomized studies carry an unclear risk of bias and most of the studies relied on the use of self-reported QoL tools, which inherently introduce recall bias, it was believed that the studies informing this evidence were of low quality. The Working Group does recognize that this is the best data available as QoL and late treatment effect data are generally not included in treatment trials a priori. However, due to the low quality of studies discovered, the Working Group decided to use both the literature and their clinical experience to summarize the late side-effects and QoL issues reported by long-term survivors of lung cancer.

RECOMMENDATION 6
For lung cancer survivors who have completed curative-intent therapy, surveillance is required and may be provided by specialists, family physicians or hospital-based nurses.

Summary of Key Evidence for Recommendation 6
The literature was searched for studies that compared follow-up care provided by a specialist with care provided by family physicians or nurses. The search returned no studies focusing on lung cancer survivors that compared family physician follow-up with specialist-led care. However, one RCT which compared hospital-based nurse-led follow-up care with specialist-led follow-up care following treatment for SCLC or NSCLC was identified (24). The study found that both QoL and recurrence outcomes were not different between the two groups, indicating that nurse-led follow-up did not negatively impact QoL or recurrence detection.

Justification for Recommendation 6
Unfortunately, the identified RCT is more than 10 years old, and when it was conducted, no effective salvage therapy and no effective second-line chemotherapy were available, which may account for the lack of difference in overall survival being detected.
Also, nurses within the study were supervised by specialists and the study allowed for additional visits to the family physician, which may have confounded some of the direct comparisons. Finally, the study included a more advanced disease population than was our target population. The Working Group considered the study limitations and even though this patient population would be managed differently today due to new treatment options, the group accepts this study as it is the best available evidence. Additionally, for this research question, QoL and satisfaction with care are highly valued. Thus, the Working Group believes that a weak recommendation for care provided by non-specialists is warranted.

**Qualifying Statements for Recommendation 6**

Although the identified literature only evaluated hospital-based nurse-led care models, expert opinion supports family physician-led care models. Additionally, family physicians should be included in all survivorship care models. There is no evidence to support timing for when lung cancer survivors can be transitioned into non-specialist care, thus no recommendation can be made for when transition is appropriate.

**RECOMMENDATION 7**

Smoking cessation counselling is recommended for patients who have completed curative-intent therapy for NSCLC and SCLC. Although verbal cessation advice from a health care professional is of benefit, interventions that involve behavioural and pharmacotherapy support in addition to verbal advice is recommended.

**Summary of Key Evidence for Recommendation 7**

Systematic reviews that assessed the efficiency of smoking cessation counselling concluded that any intervention is better than no cessation advice from a health care professional (25), and that an intensive intervention that adds further follow-up visits is more effective than brief intervention (25). When pharmacotherapy and behavioural support are added to advice from a health care professional alone, the benefit of the counselling is increased (26). The three systematic reviews and one cohort study that evaluated the benefits of smoking cessation after diagnosis of lung cancer or prior to surgery all concluded that smoking cessation improved clinical outcomes (27-30). Cohort studies that looked at the association between smoking cessation and QoL found that never-smokers reported the best QoL after curative treatment (31,32). However, patients who quit smoking within one year prior to diagnosis or during follow-up reported better overall QoL and symptom scales, compared with survivors who continued to smoke (31-33).

**Justification for Recommendation 7**

Even though none of the identified studies directly evaluated the value of smoking cessation counselling directly, the Working Group members agreed that taken together, the evidence for the benefit of smoking cessation counselling, the evidence for the benefits of cessation in lung cancer survivors and the evidence for the QoL benefits of cessation can be combined to adequately inform this recommendation.

**HOW THIS GUIDELINE CONTRIBUTES TO THE CARE OF PATIENTS**

Studies showing the benefits of surveillance after treatment for lung cancer are fairly new. For this reason, many physicians have not favoured intensive follow-up or advanced imaging because it was thought to be of little value. In the current era, improved treatment options exist, producing a larger population of lung cancer survivors and thus making follow-up more important. However, there is currently great variability in the follow-up care being
provided to lung cancer survivors in Ontario due to a lack of high-quality evidence to support one surveillance schedule. Additionally, there is a lack of high-quality evidence to inform which clinical evaluations should be performed at follow-up visits. The current evidence-based guidance document provides recommendations on appropriate follow-up schedules and evaluations for survivors of NSCLC and SCLC. This guidance document also outlines specific symptoms that may indicate recurrence or progression of lung cancer and that should be further investigated by an appropriate health care professional. Lung cancer survivors have specific post-treatment health-related QOL issues. Physicians and other health care professionals can assist patients with these issues. Finally, health care professionals can positively impact the rate of smoking cessation in lung cancer survivors by ensuring that smoking cessation counselling occurs.

FUTURE RESEARCH

High-quality literature for this topic was very limited. As such, many of the recommendations are based on clinical standards and expert opinion. Research into better salvage therapies, as well as detection of recurrent disease and second primary cancers at an earlier stage is greatly needed. Additionally, very little evidence was identified that assessed symptoms of lung cancer recurrence or development of second primary tumours. Research into these areas will allow for better guidance for health care professionals. Additionally, studies that investigate other issues experienced by cancer survivors, such as fear of recurrence, sexual health, return to work and psychosocial coping, have not been addressed in solely lung cancer survivor groups, presenting an area in need of future work. Finally, although survivorship follow-up care plans facilitate continuity of care and may minimise adverse outcomes as survivors transition into non-specialist follow-up care, care plans have not been extensively evaluated in lung cancer survivor populations, presenting another area in need of future research.

RELATED GUIDELINES

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