A Framework for Defining High-Quality Care for Patients with NSCLC

Clinical guidelines for non-small cell lung cancer (NSCLC) provide recommendations on individual components of care; however, guidance spanning the complete care pathway is lacking. In 2020, the Association of Community Cancer Centers' (ACCC) National Quality Care initiative aimed to develop quality-focused recommendations for multidisciplinary teams to identify key patient- and healthcare-centered interventions and establish a benchmark for ideal, high-quality NSCLC care.

To do so, ACCC convened a Steering Committee of multidisciplinary specialists and representation from patient advocacy and professional associations. Members were selected based on their specialized expertise, from leaders in research and/or members of medical societies or organizations dedicated to advancing care for patients with NSCLC. Additionally, engaged ACCC members nominated individuals based on their involvement and contributions to previous ACCC educational initiatives. The Steering Committee collaborated multiple times via webinars and teleconferences and provided individual feedback and comments via independent reviews over email communications and collaborative, concurrent group reviews through a Google web-based software office suite.

This steering group was then tasked with 1) compiling evidence-based recommendations via a systematic search of clinical guidelines and peer-reviewed journals and 2) proposing additional elements so that the quality-focused recommendations would encompass the entire care continuum. Specifically, the committee conducted a systematic search of published standards by quality care provision organizations; guideline repository sites, such as the National Comprehensive Cancer Network (NCCN), the European Society for Medical Oncology, and the American Society of Clinical Oncology (ASCO); and articles in peer-reviewed journals. The Steering Committee also reviewed standards from oncology accrediting organizations, including the ASCO Quality Oncology Practice Initiative and the American College of Surgeons Commission on Cancer. When guidelines were not consistent with the current recommended "best" practice(s) and/or where no formal quality metrics existed, the committee accepted expert input from oncologists. Accordingly, the Steering Committee's recommendations represented a combination of known measures

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and other evidence-based recommendations (Figure 1, below).

Quality criteria recommendations were structured to address four key care areas of the patient journey:

1. Care coordination and patient education
2. Diagnosis and biomarker testing
3. Staging and treatment planning
4. Survivorship.

Next, the Steering Committee used these recommendations to design a quality initiative framework for a national online survey of multidisciplinary cancer care teams to assess how patients with Stage III and IV NSCLC are diagnosed and managed across different United States-based cancer programs.[1] The rationale for this research was to provide a quality benchmark for cancer programs and practices by defining ideal care in different aspects of NSCLC management, with particular emphasis on multidisciplinary cancer care team management of NSCLC.

Overall, the ACCC Steering Committee developed 32 recommendations targeting key phases of NSCLC care, including:

- Involvement of a multidisciplinary team care navigator
- Patient participation in shared decision-making
- Standardized patient education on NSCLC management
- Multidisciplinary evaluation of suspicious findings
- Multidisciplinary cancer care team coordination for efficient biopsy collection
- Repeat biopsy and/or plasma testing when insufficient tissue is available
- Adoption of optimal invasive staging procedures
- Use of comprehensive biomarker testing to inform clinical decisions
- Implementation of standardized protocols for short- and long-term surveillance
- Provision of survivorship care plans.

These quality-focused recommendations define ideal, high-quality NSCLC care, serving as a valuable resource to guide multidisciplinary practice and quality improvement initiatives. As such, these recommendations were accepted for online publication as part of the ASCO Virtual Scientific Program 2020 (May 29-31, 2020) and were presented at the ASCO Quality Care Symposium (abstract 229; Oct. 9-10, 2020).

Table 1, pages 65-67, lists all 32 recommendations. Note: due to updates to NCCN Guidelines® (version 5.2021) released after this work was complete, some recommendations no longer reflect standard of care. Where appropriate, readers are referred to current clinical practice guidelines, with original recommendations appearing in blue. Cancer programs and practices should consider sharing these quality recommendations with their multidisciplinary cancer teams and using them to guide future NSCLC quality and process improvement efforts. OI

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Figure 1. ACCC Quality-Focused NSCLC Recommendations

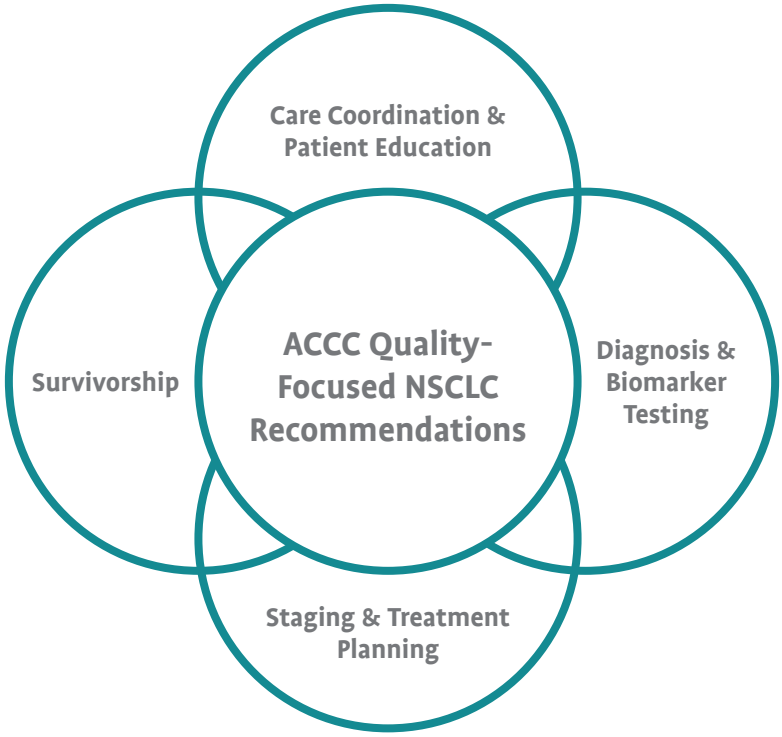

Table 1. Quality Recommendations for Ideal NSCLC Care*

Diagnosis
1.1 Screening/risk reduction
1.1.1 LDCT screening services should be made available for select high-risk smokers and former smokers who are potential candidates for definitive treatment.[2,3]
1.1.2 Institutions carrying out lung cancer screening should employ a multidisciplinary approach, including the specialties of thoracic radiology, pulmonary medicine, and thoracic surgery,[2] as determined by the anatomical location of the node.
1.1.3 Smoking cessation options should be made available to any/all interested patients, and smoking history should be documented, including both the extent of exposure in pack-years and the amount of time since smoking cessation in the case of former smokers.[2,4]
1.2 Clinical presentation/workup
1.2.1 Suspicious findings should be evaluated by an MDT comprising a medical and radiation oncologist along with a thoracic surgeon, a radiologist, and a representative from pulmonary medicine with experience in the diagnosis of lung cancer.[5,6]
1.2.2 For Stage I/II and IIIA disease, patients should undergo invasive mediastinal staging (mediastinoscopy, endobronchial ultrasound, or endoscopic ultrasound), followed by a bronchoscopy and finally surgical resection. Consider concurrent chemoradiation or chemotherapy for select Stage IIIA patients prior to surgical re-evaluation and surgery. [5,6]
1.2.3 Decisions regarding optimal diagnostic steps/biopsy and fine-needle aspiration/collection of adequate tissue should be made by an MDT comprising medical and radiation oncologists, radiologists, interventional radiologists, pulmonologists, thoracic surgeons, and pathologists with experience in the diagnosis of lung cancer. [5,6]
1.2.4 A pathologist should assess the adequacy of biopsy tissue for histologic subtype staging, as well as molecular testing and PD-L1 testing (where appropriate)[7]; a plan should be in place to rebiopsy and/or perform plasma testing if additional tissue is necessary to complete the workup.[5,6]
1.3 Evaluation
1.3.1 Determination of surgical resection, surgical staging, and pulmonary resection should be carried out by a board-certified thoracic surgeon with experience in lung cancer surgery (within the context of an MDT).[5,6]
1.3.2 At least six nodes should be removed during surgical resection, three each from the N1 and N2 stations.[5,6]
1.3.3 Systemic staging should be carried out using an FDG PET/CT scan in combination with brain MRI with contrast.[5,6]
1.3.4 Clinical staging should be carried out in line with the recommendations from the latest version of the AJCC staging manual (eighth edition).[5,6]
1.3.5 In the case of advanced or metastatic non-squamous lung cancer, refer to the most current available NCCN clinical practice guidelines for specific biomarker testing recommendations. In the case of advanced or metastatic non-squamous lung cancer, testing for EGFR, ALK, ROS1, and BRAF mutations and PD-L1 expression should be included as part of the broader molecular profiling, including emerging biomarkers for which effective drugs may already be available, such as proto-oncogene receptor tyrosine kinase (MET) amplification or mutation, rearranged during transfection (RET) rearrangements, human epidermal growth factor receptor 2 (HER2) mutations, and tumor mutational burden.[8] Additionally, testing for rare driver mutations, including the NTRK gene fusion, should be performed.[5,6,9]

Table 1 (continued). Quality Recommendations for Ideal NSCLC Care*

1.3.6 In the case of advanced or metastatic squamous lung cancer, refer to the most current available NCCN clinical practice guidelines for specific biomarker testing recommendations. In the case of advanced or metastatic squamous cancer, in addition to standard testing for PD-L1 expression and EGFR and ALK mutations, testing should be considered in never-smokers, for small biopsy specimens, or in cases of mixed histology. ROS1 and BRAF gene testing should be considered for small biopsy specimens or in specimens with mixed histology.[9] Broader molecular profiling with the goal of identifying emerging biomarkers for which effective drugs may already be available, such as MET exon 14 skipping and RET rearrangements, should be considered. Identification of rare driver mutations, including NTRK1/2/3 gene fusions, should be performed and appropriate counselling should be offered to patients on available clinical trials.[5,6]
1.3.7 Results of all biomarker tests should be returned and taken into consideration prior to making any shared clinical decisions.[5,6]
1.3.8 Processes to minimize the turnaround time for all biomarker test results should be instituted. Laboratories with an average turnaround time of greater than 10 business days should be encouraged to provide a more rapid test, either in-house or through a reference laboratory.[9]
1.3.9 cfDNA/ctDNA testing should not be used in lieu of a histologic tissue diagnosis. cfDNA/ctDNA testing may be considered in specific circumstances, such as when a) a patient is deemed medically unfit to undergo invasive tissue sampling or b) in the initial diagnostic setting, if following pathologic confirmation of an NSCLC diagnosis there is insufficient biopsy material for molecular testing and when a follow-up tissue-based analysis is planned for all patients in whom an oncogenic driver mutation has not been identified.[5,6]
Treatment
2.1 General
2.1.1 A care plan compliant with the 13 components in the Institute of Medicine (now called the National Academy of Medicine) Care Management Plan should be provided to patients prior to receipt of the first therapeutic modality.[10]
2.1.2 Palliative care should be integrated as early as possible during provision of standard oncology care services.[5,6]
2.2. Radiation
2.2.1 Determination of the appropriateness of XRT should be made by board-certified radiation oncologists with experience in lung cancer XRT (either as definitive and/or palliative treatment) within the context of the MDT.[5,6]
2.2.2 For patients managed by radiation alone, a minimum dose of 60 Gy is recommended. Dose escalation beyond 60 Gy during combined modality concurrent chemoradiation has no clinical benefits.[11]
2.2.3 In the context of combined modality therapy, chemotherapy and radiation should be given concurrently to maximize survival, local control, and disease RR.[11]
2.2.4 For patients with Stage IV NSCLC, routine use of concurrent thoracic chemoradiation is not recommended.[12]
2.3. Chemotherapy or combination treatment modalities
2.3.1 Refer to the most current available NCCN clinical practice guidelines for chemotherapy or combination treatment recommendations. Neoadjuvant chemotherapy or concurrent chemoradiation should be offered to select patients diagnosed with Stage IIIA disease,[5,6,13] adjuvant chemotherapy should be considered for patients with high-risk Stage IB/IIB disease and offered to patients with resected Stage IIIA disease, and definitive concurrent chemoradiation followed by durvalumab should be offered to patients with unresectable Stage IIIA, IIIB, and IIIC disease.[5,6,8]
2.3.2 Refer to the most current available NCCN clinical practice guidelines for chemotherapy or combination treatment recommendations. Mutation-directed TKIs should be offered to patients with advanced or metastatic NSCLC who test positive for the EGFR, ALK, or ROS1 mutation, optimally as first-line treatment options. Mutation-directed TKIs should be offered to patients with advanced or metastatic NSCLC who test positive for the BRAF V600E mutation. TKIs should be offered to patients with metastatic NSCLC who test positive for the NTRK gene fusion.[5,6]

Table 1 (continued). Quality Recommendations for Ideal NSCLC Care*

2.3.3 Refer to the most current available NCCN clinical practice guidelines for chemotherapy or combination treatment recommendations. Plasma-based testing of acquired resistant mutation T790M should be considered for patients with EGFR mutations who progress on first-line first- or second-generation EGFR TKIs. Tissue-based testing with rebiopsied tissue should be considered if results of the plasma-based tests are negative.[5,6]
2.3.4 Refer to the most current available NCCN clinical practice guidelines for chemotherapy or combination treatment recommendations. If the test results for driver mutations are negative and PD-L1 expression is ≥50 percent, patients should be offered pembrolizumab alone or pembrolizumab plus platinum-doublet chemotherapy or atezolizumab plus bevacizumab plus platinum-doublet chemotherapy for non-squamous carcinomas and pembrolizumab alone or pembrolizumab plus platinum-doublet chemotherapy for squamous carcinomas as first-line therapy for Stage IV NSCLC.[5,6,8]
2.3.5 Refer to the most current available NCCN clinical practice guidelines for chemotherapy or combination treatment recommendations. If test results for driver mutations are negative and PD-L1 expression is <50 percent, patients should be offered pembrolizumab plus platinum-doublet chemotherapy, or atezolizumab plus bevacizumab plus platinum-doublet chemotherapy, or platinum-doublet chemotherapy, or non-platinum-doublet chemotherapy, or single-agent chemotherapy for non-squamous carcinomas and pembrolizumab plus platinum-doublet chemotherapy, or platinum-doublet chemotherapy, or non-platinum-doublet chemotherapy, or single-agent chemotherapy for squamous carcinomas as first-line therapy for Stage IV NSCLC.[5,6,8]
3. Care coordination and patient education
3.1 All patients should be educated by a member(s) of the multidisciplinary cancer care team on NSCLC, diagnosis, staging, biomarker testing, prognosis, treatment plan, possible side effects, and response expectations prior to initiation of therapy.
3.2 All patients should receive care navigation as standard care and participate in SDM with regard to their comprehensive cancer care plan.
3.3 All patients should have access to a member of the multidisciplinary cancer care team who can answer questions regarding the financial aspects of their treatment plan, including, but not limited to, the need for prior authorizations and out-of-pocket costs.
4. Survivorship
4.1 Standard protocols should be instituted for chest CT scans (with or without contrast) and history and physical examinations for initial surveillance (2-5 years), followed by annual low-dose non-contrast-enhanced CT scans and history and physical examination (based on Stage at diagnosis).[5,6]
4.2 Survivorship care plans should be instituted for patients with locally advanced NSCLC treated with a curative intent.

AJCC = American Joint Committee on Cancer; *ALK* = anaplastic lymphoma kinase; *BRAF* = proto-oncogene B-Raf; cfDNA = cell-free DNA; CT = computed tomography; ctDNA = circulating tumor DNA; *EGFR* = epidermal growth factor receptor; FDG = fluorodeoxyglucose; LDCT = low-dose computed tomography; MDT = multidisciplinary team; MRI = magnetic resonance imaging; NTRK = neurotrophic receptor tyrosine kinase; PD-L1 = programmed death ligand-1; PET = positron-emission tomography; *ROS1* = c-ros oncogene 1; RR = response rate; SDM = shared decision-making; TKI = tyrosine kinase inhibitor; XRT = radiotherapy.

*Editor's Note: Due to updates to NCCN Guidelines (version 5.2021) released after this work was complete, some recommendations no longer reflect standard of care. Where appropriate, readers are referred to current clinical practice guidelines, with original recommendations appearing in blue.

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