

**STANDARD 4.6**

**MONITORING COMPLIANCE WITH  
EVIDENCE BASED GUIDELINES**

## 2016 Standard 4.6 Monitoring Compliance with Evidence Based Guidelines

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### Introduction

Lung cancer remains a leading cause of cancer death in both men and woman in the US. Based on the American Cancer Society's statistics, each year approximately 225,000 new diagnoses and more than 156,000 deaths are attributed to lung cancer. Most patients are diagnosed with advanced disease, stage IV. The median survival for patients with metastatic disease is approximately 15 months. The lung cancer five-year survival rate (17.7 %) is lower than many other leading cancer sites, such as the colon (64.4 %), breast (89.7 %) and prostate (98.9 %). More than half of people with lung cancer die within one year of being diagnosed.

There is evidence to show that when patients are treated with targeted therapy, there is notable improvement in progression free survival. For example, in patients with ALK mutations, first line therapy with crizotinib, a targeted agent, improved progression free survival, response rate (74%-45%;  $P < 0.001$ ), lung cancer symptoms and quality of life scores when compared with chemotherapy (pemetrexed with either cisplatin or carboplatin).

### Demographics

This study addresses the Standard 4.6 of Commission on Cancer. We chose to evaluate Non Small Cell Lung Cancer as the site for the **year 2015**, and addressed evaluation and therapy for specific targets, anaplastic lymphoma kinase (ALK) fusion oncogene and ROS Proto-Oncogene 1(ROS1). National guidelines (NCCN and ASCO) recommend testing for ALK and other targeted mutations in a specific set of patients: non-squamous NSCLC or NSCLC-NOS; rarely, pts with squamous histology are considered, but only if they are never smokers, small biopsy specimens were used for testing or mixed histology was reported. EGFR, KRAS, ROS1 and ALK genetic mutations do not usually overlap.

ASCO's Provisional Opinion (Beasley, 2011) reports that in community setting, where reflex testing is not routine, process requires coordination across oncologist, pathologist and potentially interventional physicians. In patients with metastatic disease, our goal is palliation of symptoms. Therapy choices include: hospice care, chemotherapy or targeted therapies such as crizotinib. Patients with ALK and ROS1 mutations should preferentially receive crizotinib or other ALK inhibitor as first line therapy.

In this study, we report how many eligible patients had appropriate testing performed, as is standard of care. If not performed, we reviewed charts to understand whether it was due to inadequacy of sample, or clinically not indicated, ie, the patient chose hospice. We hope to use this data to change our practice when appropriate. We chose this topic as we had identified potential process issues in ensuing optimal patient care during our cancer conferences.

## Methods

We used registry data to identify eligible patients with search of 2015 dataset for patients with stage IV, non small cell lung cancer, specifically adenocarcinoma.

We then reviewed our pathology database and charts to review ALK/ROS1 testing and results. When ALK/ROS1 testing was not performed, we used chart review to assess the rationale for not having the data (not ordered by oncologists, not able to performed due to sampling).

## RESULTS

There were 29 patients identified meeting eligibility described above. Chart review, pathology review shows following:

Number of patients	ALK/ROS1 Y/N	Rationale if No
16	Performed	
4	No	Hospice and pall chosen
5	No	Not able to be performed (ordered)
4	No	Unclear reasons

## Discussion

When evaluating data for ALK/ROS1 mutations, it appears that most of our patients with metastatic disease and considered eligible for therapy were screened for targeted mutations. In only 4 patients out of total 29, we were not able to confirm rationale for not having mutation studies done. For 5 patients, ALK/ROS1 mutation analysis was ordered, but inadequate sampling precluded evaluation. 4 patients deferred treatment for hospice and palliative care. While 16 patients did have mutation analysis studies, 1 had positive mutation analysis for ROS1 (total 1/29 or approximately 3%). This patient appropriately received targeted therapy with crizotinib.

## Recommendations

9 of an eligible 29 patients (5 patients with inadequate sampling, 4 patients were unable to be confirmed) were not appropriately screened for mutation analysis. While it may be reasonable to consider reflex testing for all new diagnoses of lung adenocarcinoma, testing is still done typically at the discretion of the treating oncologist. Targeted medications are not approved for early stage lung cancer, and it makes sense to defer reflex testing at this time from lung biopsies and/or resections; however, it may be a future consideration should lung adenocarcinoma be found on sampling from a metastatic site. In addition, molecular testing should also be considered in select patients with mixed histology, lung cancer NOS or squamous cell patients who meet strict criteria (ie life long nonsmokers or small sampling size).

REFERENCES:

American Cancer Society

NCCN Guidelines *Non Small Lung Cancer Version 3.2017*

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