Addressing Lung Cancer Biomarker Testing Through Project ECHO

Case Presentation Form

Instructions

This case presentation form is intended to be completed and submitted electronically. Please email completed forms along with any optional supplemental information to Kelly.durden@cancer.org and carbon copy your regional ACS staff partner. We request that you submit your case presentation form **at least three business days** prior to your scheduled case presentation. Please do NOT submit a scan of a printed version of this form.

This form includes four sections: **Section 1: Presenter Information & Case Presentation Summary**, **Section 2: System-Level Case Presentation**, **Section 3: Patient-Level Case Presentation** and **Section 4: Faculty Recommendations**. You need to complete Section 1 and then, choose **either** Section 2 or Section 3. We recommend that each case presentation will range from **three minutes to five minutes**. Please do not include patient identifiers on this form or use any identifiers during the presentation. Please note, for patient-level case presentations, the faculty will provide guidance that should NOT be interpreted as direct medical advice.

Project ECHO Data Usage Statement

Project ECHO® collects registration, participation, questions/answers, chat comments, and poll responses for some teleECHO® programs. Your individual data will be kept confidential. These data may be used for reports, maps, communications, surveys, quality assurance, evaluation, research, and to inform new initiatives.

Section 1: Presenter Information and Case Presentation Summary

1. **Presentation Date:** 11/29/2021
2. **Presenter Name(s):** Steven A Bigler
3. **Presenter Title(s):** MD
4. **Organization/Health System:** Mississippi Baptist Medical Center in Jackson
5. **Please summarize the case you are presenting to the group:** Click or tap here to enter text.
6. **Which specific questions are you asking the faculty and the other participating spoke sites?**
   How should we maximize the utility of the tiny needle core biopsy sample? What information is necessary? Which molecular results could impact primary treatment decisions for localized lung carcinoma? How can costs be minimized? Which tests will be reimbursed, and which tests will be bundled? What is the CMS "14-Day Rule" as it applies to reimbursement for molecular testing in lung cancer? What are the differences

between testing modalities- immunohistochemistry (IHC), fluorescence in situ hybridization (FISH), polymerase chain reaction (PCR), Sanger sequencing, next generation sequencing (NGS), RNA NGS?

Section 2: System-Level Case Presentation

1. **Describe your current system or workflow:** *If available, feel free to provide workflow charts separately.*

   Currently we send out for EGFR by PCR, ALK by FISH, ROS-1 by FISH, and PD-L1 by IHC on every lung cancer specimen that hasn't already had these tests.

   We send out additional testing (eg NGS, EGFR T790M, BRAF V600E mutation, Exon 14 skipping mutation) as requested by the oncology attending physician.

2. **What are the primary challenges/barriers:** *Include specifics on identified gaps and quality improvement methods used to clarify the root causes*.

   We are often dealing with very limited material, such as transthoracic needle core biopsies, cytology samples (EBUS and other), and transbronchial biopsies, which requires very careful management, and even under the most careful tissue management, we sometime don't have enough for all the tests we want.

   These tests are send-outs, which makes it more dfifficult to assure adequacy and delays turn-around time.

   Tests on in-patients are subject to the "14-Day Rule" which is cumbersome and delays results.

   NGS has certain advanatges, but is not reimbursed except in certain circumstances depending on payer, Stage, number of analytes in the panel, and potentially other factors.

3. **Describe what you are trying to improve and any other relevant background information:**

   We are analyzing the feasibility of switching from a panel of single analytes to using NGS.

   Factors influencing this decision include- 1) which analytes are actually necessary for treatment decisions for a given patient, 2) which tests can be reimbursed by MS BCBS, Medicare, and others, 3) How much do the various options cost, 4) how much material is needed to perform the testing, 5) which panel gives us the most information that we need without unnecessary testing and undue cost (e.g. NSCLC specific panel vs. a very large general panel), 6) turn-arouond time, etc.

   We need better communication between pathologists and treating physicians to make sure the correct tests are ordered on the right specimen and the right block.

4. **Briefly describe your vision of what it will look like when it is working well:**

I am planning on recommending ALK be done by IHC rather than FISH, which should be cheaper, and can potentially be done as a "technical only" test with in-house interpretation, or could be brought in-house entirely, but we need to work out the details of validation and proficiency testing before we could do any of it in-house.

I'm hoping to develop a better ordering sheet to make it easy for oncologists to choose the right test(s).

If we go to NGS testing I want to make sure that the interpretation of results is easy and useful for the treating physicians. I'm not sure how to integrate this with the standard morphology and routine IHC incorporated within the current standard surgical pathology report. We would ideally use the CAP Molecular checklist, but need to work with the oncology attendings to meet their needs.

All of this is a lot of work, which is not easily monetized, and is basically not reimbursed. It could in fact end up costing the laboratory a whole lot of money, so it will be step by step, a slow process in a rapidly changing environment.

5. **Describe any recent changes (less than 6 months) made to this system or workflow, including when they were made and their impact:**
   No recent changes; although, there has been a slight up-tick in the number of cases requesting additional testing, some NGS and some individual tests. Still, not many requests for additional testing on newly diagnosed lung cancer.

6. **If applicable, what data (quantitative, qualitative) do you have to augment your observations:**
   Moderately to poorly differentiated squamous cell carcinoma of the left lower lobe. Centrally cystic and necrotic. Measures 2.8 x 2.4 x 2.1 cm. 5.2 cm from the bronshial/vascular/hilar margin. Visceral pleura invasion, but no penetration of the pleura. Lymph nodes (13) are all **negative** (3 from Station #5, 5 from Station #7, 3 from Station 9L, and 2 from Station #10L)

Section 3: Patient-Level Case Presentation

DEMOGRAPHIC INFORMATION

1. **Age**	2. **Gender (*Choose One*)**	3. **Race/Ethnicity (*Choose All that Apply*)**	
79	Female☐ Male☒ Non-Binary/Third gender☐ Transgender female☐ Transgender male ☐	American Indian/Alaska Native ☐ Asian ☐ Black/African American ☐	Hispanic/Latino ☐ White ☒ More than One Race ☐ Other ☐

NON-SMALL CELL LUNG CANCER (NSCLC) HISTOLOGY & STAGE

4. **Diagnosis**	5. **Histology**	6. **Stage**
Initial Diagnosis ☒ Recurred and or Progressed ☐	Adenocarcinoma ☐ Squamous Cell ☒ Large Cell ☐	pT2a pN0 AJCC Stage/Prognostic Group IIa

BIOMARKER TESTING

7. **Has biomarker testing been ordered for this patient (or will it be ordered)?**	8. **If biomarker testing was not ordered, please elaborate on the factors that precluded it:**
Yes ☒ No ☐ Will be ordered ☐	Click or tap here to enter text.

The next section is ONLY for those patients who HAVE received or WILL receive biomarker testing

9. **Which technique was used (or will be used) to obtain specimen for pathologic diagnosis? *(Choose One)***

Bronchoscopic biopsy ☐ Endobronchial ultrasound-guided transbronchial lymph node aspiration (EBUS-TBNA) ☐ Image-guided percutaneous biopsy ☒ Liquid biopsy ☐	Mediastinoscopy ☐ Surgical specimen ☐ Thoracentesis/pericardiocentesis ☐ Unsure ☐

10. **Which platform was/will be used for lung biomarker testing? *(Choose One)***	11. **If single-gene test or short-cluster panel, please identify which genes were tested:**		
Single-Gene Test ☐ Short-Cluster Panel ☐ Multi-Gene Panel (next generation sequencing (NGS) ☐	ALK ☒ BRAF ☐ EGFR ☒	HER2 ☐ KRAS ☐ NTRK ☐ MET ☐	PD-L1 ☒ ROS1 ☒ RET ☐

ADDITIONAL INFORMATION

12. **Please include any other information you would like to share with the group:**
EGFR: Mutation not detected (PCR), ALK: Negative by FISH, ROS-1: Negative by FISH, and PD-L1: Tumor Proportion Score (TPS) >90%

Section 4: Faculty Recommendations

This section will be completed by the ACS ECHO Coordinator. Recommendations from our faculty will be documented below.

Click or tap here to enter text.

Assigned Case Presentation Number: Will be assigned by ACS