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:** 6/28/2021
2. **Presenter Name(s):** Phil Lammers
3. **Presenter Title(s):** MD
4. **Organization/Health System:** Baptist Cancer Center
5. **Please summarize the case you are presenting to the group:** System lung cancer NGS testing strategy
6. **Which specific questions are you asking the faculty and the other participating spoke sites?**
   Have others implemented a large scale NGS testing process and what feedback can you give for the implementation process?

Section 2: System-Level Case Presentation

1. **Describe your current system or workflow:** *If available, feel free to provide workflow charts separately.*
   Over the past year, we have developed a relationship with a vendor to provide lung cancer NGS testing for our patients. We have implemented direct ordering and reporting into our EPIC EMR. We are now working on implementing the genomic module with EPIC to get the results in discreet data format to use for generating reports and identifying patients for treatments/clinical trials.

   Our next step will include reflex testing for all patients diagnosed with lung cancer working with our pathology group partners throughout our system.

2. **What are the primary challenges/barriers:** *Include specifics on identified gaps and quality improvement methods used to clarify the root causes.*
   Many physicians have used other vendors in the past and have not wanted to switch their processes for ordering. There have been challenges to work out processes of ordering through our EMR. There will be a challenge in working with the various pathology group partners that we have across our system to implement reflex testing on lung cancer specimens.

3. **Describe what you are trying to improve and any other relevant background information:**
   We are trying to increase the number of patients that have NGS testing on their samples to open up better opportunities for appropriate treatments and opportunities for clinical trials.

4. **Briefly describe your vision of what it will look like when it is working well:**
   When this is fully operational, I envision that we will be able to identify patients quickly for appropriate targeted therapies and/or immunotherapies across the spectrum of stage of lung cancer and across our entire system to ensure no patient with lung cancer is left out. We will enhance our multidisciplinary care and our clinical trials program in the process.

5. **Describe any recent changes (less than 6 months) made to this system or workflow, including when they were made and their impact:**
   Over the last 3 months, we have piloted ordering of our vendor's platform into our EPIC EMR and receiving those results directly into the EMR from a few clinics. This week, we have activated this process system-wide across Mississippi, Tennessee, and Arkansas.

6. **If applicable, what data (quantitative, qualitative) do you have to augment your observations:**
   None to date

Section 3: Patient-Level Case Presentation

DEMOGRAPHIC INFORMATION			
1. **Age**	2. **Gender (*Choose One*)**	3. **Race/Ethnicity *(Choose All that Apply)***	
Click or tap here to enter text.	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 ☐	Click or tap here to enter text.	
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:** Click or tap here to enter text.			

Section 4: Faculty Recommendations

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

Highlights from Case Presentation Discussion

What was your process and or criteria for choosing the specific vendor?

- Baptist has alliances with other institutions, work closely with Vanderbilt; leaned heavily into their expertise.
- Our personal experiences in working with different vendors
- Piloting with certain vendor
- Criteria included: Cost, turnaround time, support in clinic, interpretation of results, access to molecular tumor board, quality, and reputation (of the vendor)

How will you manage the costs of the reflex testing on all lung cancer specimens? Especially for the un and underinsured.

Negotiating at the institutional level creates economies of scale that allow vendors to be more likely to collaborate, which saves time, ensures uniformity of access. It is important to take an institutional approach to solve this problem, rather than having individual MDs deal with it. Health plans are complex. Very sensitive to costs to our patients and passing it. This vendor (and many of them now) have patient programs. About 75% of patients pay nothing (at Baptist).

Can you comment on how reflex testing will work in terms of the ordering physician. Will it be the pathologist or the treating physician?

Baptist: We have not completed the process. Interested in hearing how others have overcome this issue as we look to implement on a larger scale.

UK Markey: Reflex testing works best when pathologist orders but becomes a problem regarding who will conduct the follow up. Interested in the best way as well. Reflex testing for molecular testing is complex. Nurse navigator is helpful to overcome these challenges, anticipating these cases and starting the paperwork early (consent forms, billing, etc.)

Northside Cancer Institute: Adhoc committee decide what testing, ordering physician will be pathologist.

Will Reflex Testing be done for everyone or by stages?

Still working out the details; may make sense for all patients. Cost and reimbursement are big issues. With the recent ADAURA trial and the opportunity to identify patients for clinical trials, it may make sense to push for full panel, including PD-L1 for all patients. We need to standardize some of the reporting. Ensure physicians and patients understand the results through molecular tumor boards.

Comment: Risk of too much information, e.g. receiving information that will not be used or helpful.

How do you handle 14-Day Rule?

Baptist: More and more we are doing liquid biospies. Liquid biospy (blood test) makes the turnaround time shorter (still may need to obtain tissue in some cases).

UNC at Chapel Hill (Dr. Rivera): We (UNC at Chapel Hill) are not using liquid biospies upfront; we use liquid biospies when we simply cannot obtain tissue (patient does NOT want it or cannot for other clinical reasons). We do use liquid biopsies more now for patients when they relaspe. There is an ongoing study by Biodesix regarding utilizing liquid biospies at the time of diagnois compared to tissue.

Agree on clarification of testing of all stages. It's not a practice at UNC (only Stage IV disease). At what point, do we

begin on all patients? More studies are emerging. We need to make it it less challenging and much more succint for patient care.

Question for Dr. Rivera: Do you have the rate of incomplete molecular testing in the initial biospy in tissue at your institution?
Not readily available. We are looking at this, as we are part of this study (tissue versus liquid). We have had excellent success with moledular biomarker testing with fine needle aspiration. CAP, IASLC, and AMP 2018 guidelines as reference.

I have some concerns about having centrally mandated vendors with no input in the choice of vendors. Concerns regarding objectivity of vendor choice are amplified when a small number of people decide for everyone.
Faculty Response: Important to engage early in the dialogue, so that your solution can be based on consensus.

Sometimes vendors want to charge the ordering institution rather than patients for a variety of reasons. Who pays for the test when it's not insurance? My lab managers don't have a budget to pay for NGS testing for every lung cancer.
Baptist: The vendor we use eats the cost of the test if not covered by insurance and limit costs to the patient. No cost put on laboratories

Additional questions from faculty to consider regarding the case presentation:
- How will you handle situations with inadequate tissue for testing? Will you reflex to a liquid biopsy?
- How do you plan to "enforce" the use of a single vendor

Assigned Case Presentation Number: 1.0