NCCN Tumor Board Curriculum: Molecular Testing in Non-Small Cell Lung Cancer

Patient Navigation: Role in Molecular Testing in NSCLC

Presented by:

Teresa Knoop, MSN, RN, AOCN
Assistant Director, Clinical Trials Shared Resource
Vanderbilt-Ingram Cancer Center

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This activity is supported by educational grants from Genentech, USA and Pfizer.

Accreditation Information

- Please use the Q&A feature on the right-hand portion of your screen for any clinical questions and logistical concerns you have regarding the session. This is the only online method of communicating questions or concerns. Should you need additional assistance please e-mail education@nccn.org or call 215-690-0300 and ask to be connected with someone in the NCCN Conferences and Meetings Department.
- Credit will be provided to physicians, nurses, and pharmacists (1.0 contact hour) through completion of an evaluation and post-test. All registered participants will receive an e-mail from our CE and Grants Department within 3-5 business days with instructions on how to access this evaluation and post-test at http://education.nccn.org/node/42527. Certificates will be generated automatically upon successful completion of this step. Should you not receive an e-mail within 5 days, please contact us at education@nccn.org.

Accreditation Information

- It is required by the ACCME that all educational activities are designed to change participant ***competence, performance, or patient outcomes.***
- To meet this requirement, NCCN asks that all participants complete the outcomes measures described below:
  - The post-test and evaluation as indicated in e-mail you will receive within 3-5 business days of the conclusion of this activity. This is required to receive credits or your certificate of completion. You must be registered in advance to receive credits or certificate. Certificates will be generated automatically upon successful completion of this step.
    - There will be a separate WebEx evaluation at the conclusion of this program, which is optional and does not go to NCCN.
  - The follow-up post test (to be sent 30 days after the activity has ended to demonstrate an increase in participant competence)
  - The follow-up survey (to be sent 60 days after the activity has ended to demonstrate an increase in participant performance)
- NCCN greatly appreciates your compliance with completing the aforementioned post-test and surveys. All of these measures will be available by logging into your account at http://education.nccn.org. Reminder e-mails will be sent to the participants via e-mail. If you have any questions or concerns, please e-mail education@nccn.org.

Accreditation Information

- If you participated with a group of peers, a list of everyone who attended in your group must be submitted within two weeks of the activity in order for the participants to be eligible to receive credit. This list is in addition to individual registration. Attendee lists will not be accepted after two weeks post-activity. Lists can be sent to education@nccn.org and should contain full contact information for each participant, including first and last name, credentials, mailing address, phone number, and e-mail address.
- If you have not individually registered, please register at: http://www.cvent.com/d/84qzdg

Accreditation Information

While NCCN is pleased to respond to as many questions as possible during this webinar, NCCN will not be able to respond to your individual questions of a clinical nature after the webinar has concluded. We are also not able to offer recommendations on patient care regarding specific cases.

Accreditation Information

Intended Audience:

This webinar series is designed to meet the educational needs of medical oncologists, radiation oncologists, surgical oncologists, pathologists, nurses, pharmacists, and other healthcare professionals who manage patients with non-small cell lung cancer.

Learning Objectives:

Following this program, participants should be able to:

- Develop core communication messages for use with patients in advance of testing decision making

Accreditation Information

Physicians
The National Comprehensive Cancer Network (NCCN) is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

NCCN designates this live activity for a maximum of *1.0 AMA PRA Category 1 Credit(s)™.* Physicians should only claim credit commensurate with the extent of their participation in the activity.

Nurses
The National Comprehensive Cancer Network is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

This activity is accredited for 1.0 contact hours. Accreditation as a provider refers to the recognition of educational activities only; accredited status does not imply endorsement by NCCN or ANCC of any commercial products discussed/displayed in conjunction with the educational activity.

Kristina M. Gregory, RN, MSN, OCN, is our lead nurse planner for this educational activity.

Accreditation Information

Pharmacists

National Comprehensive Cancer Network is accredited by the Accreditation Council for Pharmacy education as a provider of continuing pharmacy education.

Type of Activity
Knowledge

Credit Designation
National Comprehensive Cancer Network designates each of these continuing education activities for 1.0 contact hour(s) (0.1 CEUs) of continuing education credit in states that recognize ACPE accredited providers.

(UAN: 0836-0000-14-046-L01-P)

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If you have any questions, please e-mail education@nccn.org.

Accreditation Information

The ACCME/ANCC/ACPE defines “conflict of interest” as when an individual has an opportunity to affect CE content about products or services of a commercial interest with which he/she has a financial relationship.

ACCME, ACPE, and ANCC focuses on financial relationships with commercial interests in the 12-month period preceding the time that the individual is being asked to assume a role controlling content of the CE activity. ACCME, ACPE, and ANCC have not set a minimal dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship. The ACCME, ACPE, and ANCC defines “‘relevant’ financial relationships” as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

All faculty for this continuing education activity are competent in the subject matter and qualified by experience, training, and/or preparation to the tasks and methods of delivery.

Nurse Planner: Kristina M. Gregory, RN, MSN, OCN is the nurse planner for all NCCN educational activities.

Faculty Disclosures

All faculty and activity planners participating in NCCN continuing education activities are expected to disclose any relevant financial relationships with a commercial interest as defined by the ACCME’s, ANCC’s, and ACPE’s Standards for Commercial Support. All faculty presentations have been reviewed for adherence to the ACCME’s Criterion 7: The provider develops activities/educational interventions independent of commercial interests (SCS 1, 2, and 6) by experts on the topics. Full disclosure of faculty relationships will be made prior to the activity.

The faculty listed below have no relevant financial relationships to disclose:

Teresa Knoop

Planning Staff Disclosures

NCCN DISCLOSURES

The activity planning staff listed below has no relevant financial relationships to disclose:

Robert W. Carlson, MD; Ann Gianola, MA; Mark Geisler; Kristina M. Gregory, RN, MSN, OCN; Kristin Kline Hasson; Joan S. McClure, MS; Diane McPherson; Melanie Moletzsky; Deborah Moonan, RN, BSN; Liz Rieder; Shannon K. Ryan; Shannon Scarinci; Jennifer McCann Weckesser

The activity planning staff listed below has disclosed the following relevant financial relationships:

Valesta Tejan-Kamara
AstraZeneca Pharmaceuticals: Stock/Shareholder

The NCCN clinical information team listed below, who have reviewed content, have no relevant financial relationships to disclose:

Kristina M. Gregory, RN, MSN, OCN
Miranda Hughes, PhD

Faculty

Teresa Knoop, MSN, RN, AOCN, is an Assistant Director at the Vanderbilt-Ingram Cancer Center in Nashville, TN, where she supervises the Clinical Trials Information Program. The program serves as the referral center for Phase I, II, and III trials at the center and provides healthcare professionals and consumers with services, specialists, and second opinions. Ms. Knoop also directs special projects related to clinical research integration and Phase I program growth and development.

Ms. Knoop received her BSN from Murray State University in Murray, KY, and her MSN from the Vanderbilt School of Nursing in Nashville, TN. She is an active member of ONS on the local and national level, where she has spoken at numerous conferences, coordinated sessions, and helped to design the ONS Speaker Training Program. Her areas of expertise include clinical trials, the use of novel targeted agents in the treatment of cancer, and non–small-cell lung cancer.

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Patient Navigation: Role in Molecular Testing in NSCLC

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Objective

- Develop core communication messages for use with patients with non-small cell lung cancer (NSCLC) in advance of testing decision making.

Core Communication Messages

- Stage/current disease state/histology
- What does molecular tumor testing mean?
- Is molecular testing appropriate for every patient's case? Why or why not?

Core Communication Messages

- What information will molecular testing provide and what will it not provide?
- How is molecular testing done?
- Why might additional biopsies be required and what will be entailed?

Core Communication Messages

- How long is the waiting time for molecular testing results?
- How are the results interpreted and how will those results drive treatment decisions?
- How does molecular testing help drive available standard of options and clinical trial options?
- What does this information mean now and what might it mean for the future?

Stage/Current Disease State/Histology

- Stage at diagnosis
- Current disease state
  - Newly diagnosed
  - Recurrence/metastasis
- Histology of NSCLC
  - Adenocarcinoma, large cell carcinoma, and NSCLC not otherwise specified (NOS)
  - Squamous cell carcinoma
- Goal of current treatment

What does molecular testing mean?

- Molecular testing is a way to look at the tumor at a molecular level to determine if there are any biomarkers that can predict whether the patient will receive therapeutic benefit from a drug. (predictive biomarkers)
- Epidermal growth factor receptor (EGFR) mutations and anaplastic lymphoma kinase (ALK) gene rearrangements are 2 commonly recommended molecular tests for non-small cell lung cancer

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Is molecular testing appropriate for every patient's case? Why or why not?

- Decisions to do molecular testing may depend on:
  - Where patient is in disease trajectory
  - What the sub-type is for their NSCLC
    - Adenocarcinoma, large cell carcinoma, and NSCLC not otherwise specified (NOS): EGFR and ALK
    - Squamous cell carcinoma: if it is squamous cell, then the recommendation is to only do EGFR/ALK testing if the patient is a never smoker, has mixed adeno-squamous histology or if only a small specimen (not a resection) was done for histology testing (with small specimens, it could be a mixed adeno-squamous and be missed due to the small size of the specimen)

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What information will molecular testing provide and what will it not provide?

- Molecular testing for NSCLC will provide:
  - Information about gene alterations (mutations or alterations) in the patient's tumor that predict whether the cancer will be sensitive to certain drugs or whether those drugs are not likely to help in that patient's situation due to a lack of gene alterations
- Molecular testing for NSCLC will not provide:
  - A guarantee that the drugs given for the genetic alterations will cure the cancer; tumors often develop resistance to these drugs after a period of time
  - Information about hereditary risk for other members of the family

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How is molecular testing done?

- To perform molecular testing on patients with NSCLC currently it:
  - Must be done via a sample of the patient's tumor tissue; can be done on archived tissue
  - Cannot be done on a blood sample
  - May be done on the primary site of the tumor or on a metastatic site
  - Must be done on a large enough specimen of tissue. Fine needle aspirations often do not provide enough tissue for molecular testing
  - Should be done with an effort in pathology to use enough tissue to accurately diagnose the case, while conserving enough tissue to perform molecular testing

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Why might additional biopsies be required and what will be entailed?

- If a patient needs molecular testing done to be able to choose the most appropriate treatment plan, then an additional biopsy may be needed. Common in the clinical trial setting
- Additional tissue may be needed if the initial biopsy did not yield enough tissue for both histologic diagnosis and molecular testing
- The least invasive biopsy type that can yield the amount of tissue needed will be chosen
- Types of procedures may include: biopsy of lymph node or an organ such as liver; bronchoscopy; mediastinoscopy

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How long is the waiting time for results?

- Waiting time variable and can be anxiety producing
- What can alter the waiting time?
  - Will the testing be done in your institution or sent out to an independent lab?
  - Is enough tumor tissue available in your pathology department?
    - If not, the archived tumor tissue may have to be obtained from a different institution which increases time frame
  - Is enough tumor tissue available?
    - If not, the patient may need another biopsy which will increase time frame

How are the results interpreted and how will those results drive treatment decisions?

- EGFR results are interpreted by looking at the tumor DNA via multiplex polymerase chain reaction (PCR) systems
- EGFR is often done together with a mutation screening assay panel that looks at a multitude of biomarkers simultaneously for point mutations
- PCR systems do not detect gene rearrangements so ALK has to be tested differently through a procedure known as FISH (fluorescence in situ hybridization) and may be done by a different lab
- Having these results for EGFR and ALK will help the MD and patient make the best treatment decisions

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How does molecular testing drive available standard of options and clinical trial options?

- In NSCLC, there are currently FDA approved drugs that target gene alterations present in the patient's tumor. Presence or absence of these gene alterations can help determine what drugs may be most efficacious for each patient and which drugs are not likely to be effective
- FDA approved drugs for patients with EGFR mutations
  - erlotinib
  - afatinib
  - gefitinib (not widely available in the United States)
- FDA approved drug for patients with ALK rearrangements
  - crizotinib

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How does molecular testing drive available standard of options and clinical trial options?

- In NSCLC there are many clinical trials being conducted across the United States exploring other driver mutations or alterations that can be targeted by drugs (druggable targets)
- Targets of interest for NSCLC include:
  - HER2 (ERRB2)
  - BRAF
  - ROS1 and RET gene rearrangements
  - MET amplifications
- Next generation gene sequencing is looking at large numbers of genes

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What does this information mean now and what might it mean for the future?

- Molecular testing many mean little in terms of immediate treatment options to some patients, particularly if their disease is not advanced. However, may be needed for the future in case of disease recurrence
- Molecular testing results may mean immediate treatment options for some patients in terms of:
  - Standard treatment
  - Clinical trials

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Resources for Health Care Professionals

- Genetics/Genomics Competency Center (G2C2) developed by the National Human Genome Research Institute (NHGRI)
  - http://www.g-2-c-2.org/
- International Society of Nurses in Genetics (ISONG)
  - *www.**isong**.org*
- Mycancergenome.org
  - http://mycancergenome.org
- National Comprehensive Cancer Network
  - http://NCCN.org
- Oncology Nursing Society
  - http://ONS.org

Reference

- National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Guidelines. Version 3.2014. http://NCCN.org. Retrieved April 6, 2014.

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Please Remember!

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- If you have not individually registered, please register at: http://www.cvent.com/d/t4q1g6
- Handouts can be downloaded at: **http://nccn.webex.com/event**. You must display past events and search by date and time for today's webinar.
- An e-mail will be sent within 3-5 business days with instructions on how to login to complete post-test and evaluation. These must be completed in order to receive a CE certificate. Contact **education@nccn.org** should you not receive this e-mail within 5 business days.
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Roswell Park Cancer Institute

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