

Consistent Testing Terminology Use Cases Workshop

March 11, 2021

Consistent Testing Terminology Working Group

PATIENT ADVOCACY GROUPS



PROFESSIONAL SOCIETIES



INDUSTRY PARTNERS



Use Case – Pancreatic Cancer

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Use Case: Pancreatic Cancer

Presenter: Pancreatic Cancer Action Network

Biomarkers in Pancreatic Cancer

- About 60,430 individuals will be diagnosed with pancreatic cancer in 2021¹
- Currently the 5-year survival rate is 10%¹
- Biomarkers for Risk²: APC, ATM, BRCA1, BRCA2, CDKN2A, CFTR, CHEK2, MLH1, MSH2, NBN, PALB2, PALLD, PRSS1, SPINK1, TP53
 - ~10% of those with pancreatic cancer inherited a biomarker that increased their risk of developing the disease³
- Biomarkers for Treatment: BRCA1/2, MSI-H, dMMR, High TMB, NTRK fusion

1. Facts and Figures 2021, American Cancer Society

2. Zhan W, Shelton CA, Greer PJ, Brand RE, Whitcomb DC. Germline Variants and Risk for Pancreatic Cancer: A Systematic Review and Emerging Concepts. *Pancreas*. 2018;47(8):924-936. doi:10.1097/MPA.0000000000001136

3. Pancreatic Cancer Risk Factors. American Cancer Society. <https://www.cancer.org/cancer/pancreatic-cancer/causes-risks-prevention/risk-factors.html>. Published June 9, 2020. Accessed February 18, 2021.

Use Case: Pancreatic Cancer

Biomarker Impact on Diagnosis & Treatment

- There is not currently a biomarker used to diagnose pancreatic cancer
 - Some surveillance studies enroll individuals with genetic mutations that are known to increase risk of exocrine pancreatic cancer.
- Chemotherapy regimens are commonly used for neoadjuvant/adjuvant treatment, as well as for advanced cancer
- Although 25% of patients have an actionable mutation, the use of biomarker targeted therapies is extremely limited
 - Individuals with an inherited BRCA1/2 mutation, who have responded to platinum agent chemotherapy for at least 4-6 months may receive Olaparib maintenance therapy⁴
 - Individuals with a tumor that is MSI-H, dMMR or has a High TMB may receive pembrolizumab
 - Individuals with a tumor that have an NTRK gene fusion may receive entrectinib or larotrectinib
- During 2011-2019, there were 5-14 pancreatic cancer specific trials open in a given year that required biomarker testing for enrollment⁵

4. National Comprehensive Cancer Network. Pancreatic Adenocarcinoma (Version 1.2021). https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf. Accessed February 18, 2021.

5. Manuscript in preparation

Use Case: Pancreatic Cancer

Recommendations for Genetic & Biomarker Testing

- National Comprehensive Cancer Network guidelines recommend:
 - Genetic testing for all patients diagnosed with an exocrine pancreatic cancer
 - NCCN guidelines refer to genetic testing as *germline testing*.
 - Genetic testing for first degree relatives of pancreatic exocrine patients when the pancreatic cancer patient was not able to undergo genetic testing
 - Cascade testing is also recommended⁶
 - Biomarker testing for locally advanced/metastatic pancreatic cancer⁴
 - NCCN guidelines refer to biomarker testing as *gene profiling* and also *tumor/somatic gene profiling*.

4. National Comprehensive Cancer Network. Pancreatic Adenocarcinoma (Version 1.2021). https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf. Accessed February 18, 2021.

6. National Comprehensive Cancer Network. Genetic/Familial High Risk Assessment: Breast, Ovarian, and Pancreatic (Version 2.2021). https://www.nccn.org/professionals/physician_gls/pdf/genetics_bop.pdf. Accessed February 18, 2021.

Use Case: Pancreatic Cancer

Implementation of Consistent Testing Terminology Guidelines

- We audited our website and the materials in our call center (Patient Central) for relevant language using our prior terminology (“molecular profiling,” “germline testing”).
- We then modified the language on our website and the materials shared to conform to the two terms selected by the working group (“biomarker testing” and “genetic testing for inherited risk”).
- At the time our materials were updated, we sent out email communication and posted an article on our blog which used the new terminology.

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Implementation Challenges

- A biomarker testing service that we offer to patients (Know Your Tumor[®]) uses an IRB-approved informed consent form and recruitment script which contains the old terminology.
 - Updating this has been delayed due to competing priorities. For the time being, our team is using both our old terminology and new terminology when talking about the testing service, because we have not yet updated the informed consent form and recruitment language and submitted it for formal review.
- IRB-approved Patient Registry platform is undergoing a transition to a new platform, so also contains old terminology.
- Internal systems that our Patient Central case management team utilizes also contain old terminology due to competing resources and priorities.

Use Case: Pancreatic Cancer

Barriers that Remain

- Genetic/biomarker testing companies still use their own terminology. When providing information about these companies and their tests to patients, there is the potential for some confusion.
- With a lack of approved biomarker-driven therapies, biomarker testing is less compelling in this disease.
- NCCN guidelines utilize other terminology, i.e., germline testing, gene profiling of tumor tissue, tumor/somatic gene profiling.