

PRECISION MEDICINE: INTEGRATION OF PATHOLOGY WITH THE CANCER CARE TEAM



WORKSHOP OUTCOMES

For this project, the Association of Community Cancer Centers (ACCC) coordinated three virtual workshops at the following member programs:

| Cancer Program | Location | Date | Faculty |
|--------------------------------------------------------|----------------|----------|-------------------------|
| Cotton O'Neil Cancer Center, Stormont Vail Health | Topeka, KS | 06.23.21 | Vivian Pan, MS, CGC |
| Cone Health Cancer Center | Greensboro, NC | 07.22.21 | Vivian Pan, MS, CGC |
| Summerlin Hospital Cancer Center, Valley Health System | Las Vegas, NV | 09.21.21 | S. Michelle Shiller, DO |

Workshop Goal: Explore ways to improve processes regarding hereditary genetic counseling and testing for cancer prevention, targeted treatment selection, and family support.

Verbatim feedback from workshop participants:

- *"This is a changing landscape, and it is important to recognize the impact of genetic/ biomarker testing on patients. This is especially true now that test results and pathology reports go directly to patients."*
- *"The discussion with the interdisciplinary team as a whole was great. The different perspectives between departments and providers were very insightful."*
- *"We can do better with respect to genetic testing and biomarker discussions with patients and among disciplines/consults."*
- *"Learned a lot about the different tests and the significance of treatment options based on genetic abnormalities."*

Increased Demand for Genetic Counseling and Testing

During the workshops, the participating cancer programs indicated they were seeing an increased demand for genetic counseling and testing. At Cotton O'Neil, the team had been working to improve the identification of patients with breast cancer who may be eligible for genetic testing. They were in the process of incorporating a hereditary risk assessment for every new patient with breast cancer. Patients received genetic counseling through telehealth platforms. At Cone Health, the cancer center formed a partnership with the University of North Carolina Greensboro to increase genetic counseling education, training, and research opportunities. At Summerlin Hospital, one of the medical oncology groups hired three genetics professionals to improve access for patients who require genetic counseling.

Workshop participants agreed that the adoption of telehealth has increased access to genetic counselors. However, they added that there are still opportunities to identify and refer patients who may be eligible for genetic testing. Patients who were discussed at a multidisciplinary tumor board were more likely to be identified and referred to for genetic testing. Some of the workshop participants held several different types of tumor boards, and they indicated that it would be valuable to add a discussion about the role of genetic testing for various types of cancers.

Among the workshop participants, several noted that certain patients were not consistently receiving timely genetic counseling and testing. Examples included the following:

- Some urology groups that manage patients with prostate cancer may not order genetic testing for them. These patients are often not discussed at a tumor board, may not be referred to medical oncology for co-management, or may miss opportunities to be treated with PARP inhibitors.
- In some institutions, genetic testing may be ordered by surgeons, medical oncologists, or other providers. If test ordering is not coordinated and communicated across members of the cancer care team, it may be delayed. Tumor boards offer a mechanism to coordinate this type of testing, but many patients are not discussed at tumor boards.

Several workshop participants also noted the challenges associated with billing, reimbursement, and health insurance coverage for biomarker testing, genetic counseling, and genetic testing.

Terminology

During the workshops, participants also agreed that the terminology of genetic testing may be confusing to clinicians and patients. Patient charts may indicate that "molecular or gene testing" was performed, but it may not be clear whether this refers to somatic biomarker testing or germline genetic testing. Participants agreed that patients are often confused about the differences between somatic vs. germline testing. Some patients may not understand that germline testing may provide actionable therapeutic and prognostic information (e.g., BRCA and targeted therapy with PARP inhibitors, TP53 and future cancer risk with radiation, BRCA and risk for contralateral breast cancer and ovarian cancer, etc.).

With the increased use of broad genomic profiling (next-generation sequencing) for biomarker testing, clinicians indicated that there were times when the test reports would indicate the possibility of an underlying germline mutation. Some physicians were sending samples to labs that perform concurrent somatic and germline testing. Others agreed they should inform patients who undergo NGS biomarker testing that they may also need germline testing based on their test results.

Improvement Opportunities

The 2020 CoC Standards Section 4.4 Genetic Counseling and Risk Assessment require the cancer committee to document annual evaluations of their genetic counseling and risk assessment services. The 2018 NAPBC Standard 2.16 Genetic Evaluation and Management requires certification/credentialing for cancer genetics professionals who perform genetic counseling and require documented annual continuing education credits obtained by these professionals.

After the workshop, a post-program evaluation was sent via email and the following table summarizes their responses:

| Topic | Plan to make moderate or significant changes to improve their processes |
|------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| Identifying patients with cancer who may be eligible for genetic testing for an inherited mutation | 63.7% (n=11) |
| Ordering biomarker testing and/or genetic testing for an inherited mutation for patients with cancer | 54.6% (n=12) |
| How patients access genetic counselors who can provide pre-test and/or post-test genetic counseling | 66.7% (n=12) |
| How patients are notified if/when their genetic test results are reclassified | 33.3% (n=12) |
| Incorporating more discussions during tumor board meetings about genetic testing for an inherited mutation | 66.7% (n=12) |

The following is a list of potential improvement opportunities based on workshop discussions and feedback from participants:

- Increase the identification of patients who may be eligible for genetic counseling and testing by incorporating a systematic approach (e.g., hereditary risk assessment) into every new patient visit.
- Coordinate test ordering among members of the cancer care team so testing is not delayed. The tumor board may be one place to coordinate communication about testing. Navigators may also facilitate communication.
- Leverage both telehealth resources and face-to-face visits to offer more pre-test genetic counseling so patients understand the importance and clinical relevance of testing.
- Provide ongoing staff education about the evolving landscape of cancer genetics and the role of genetic testing.
- Hold a dedicated “hereditary cancer tumor board” during which specific cases can be discussed. This would also offer the multidisciplinary care team a place to identify and discuss potential process improvement opportunities.

- Establish consistent terms for phrases such as “biomarker testing,” “genetic testing for an inherited mutation,” and “genetic testing for inherited cancer risk” to establish the differences between somatic vs. germline testing.
- Find ways to clarify whether test results in the EHR are for somatic vs. germline tests.
- Inform patients that NGS biomarker testing may reveal potential germline mutations.
- Enhance coordination with the urological services team to conduct biomarker testing.
- Consistently communicate with genetic counselors in nearby practices.

Conclusion

As more patients with cancer undergo both biomarker testing and genetic testing for inherited mutations, there is a growing opportunity to refine procedures and provide ongoing staff education. Most community cancer programs do not have a molecular pathologist on staff. Many also lack on-site genetic counselors. The increasing adoption of telehealth has allowed patients to have more access to genetic counseling, but there is an ongoing need to ensure that the right patients are identified and referred for testing in a timely fashion. The ACCC workshops allowed cancer programs to evaluate their current processes, learn about relevant updates in cancer genetics, and identify opportunities for process improvement.

Baseline Survey

Rating scale (1-3; higher is better); NS = not sure

| | Site 1 | Site 2 | Site 3 |
|------------------------------------------------------------------------------------------------------------------|------------|--------------------|---------------|
| Location | Topeka, KS | Greensboro, NC | Las Vegas, NV |
| Setting | Urban | Urban/ Suburban | Urban |
| New cancer diagnoses per year | >1k | >1k | >1k |
| Participation and engagement of pathologists during clinical case conferences and tumor boards | 3 | 3 | 3 |
| Participation and engagement of pathologists during administrative meetings | 3 | 1-3 | 3 |
| Involvement of pathologists in leadership roles within the organization | 3 | 1-3 | 3 |
| Availability of rapid-on-site evaluation (ROSE) by pathologists or technicians when specialists perform biopsies | 2 | 3 | 3 |
| Access to patient charts by pathologists who are making a cancer diagnosis | 3 | 3 | 3 |

| LUNG | | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--------------------|---------------|
| | Site 1 | Site 2 | Site 3 |
| Location | Topeka, KS | Greensboro, NC | Las Vegas, NV |
| Setting | Urban | Urban/ Suburban | Urban |
| Expertise and experience among pathologists who make a lung cancer diagnosis | 3 | 2-3 | 3 |
| Quality and completeness of solid tumor pathology reports when a new cancer diagnosis is made; reports follow the College of American Pathologists (CAP) Cancer Protocol & Biomarker Templates | 3 | 3 | 3 |
| Gaps or breakdowns in communication (e.g., inaccurate, insufficient, or incomplete information) between pathologists and other members of the cancer care team when lung cancer biomarker tests are ordered | NS | 3 | 3 |
| Quality and adequacy of needle biopsy samples for lung cancer diagnosis and biomarker testing | NS | 3 | NS |
| Timeliness of obtaining lung cancer biomarker test results (less than ten business days between sample receipt and reporting of all results) that may impact treatment decisions | NS | 2-3 | 2 |
| The cancer program has policies to govern the appropriate use of broad genomic profiling using next-generation sequencing (NGS) | 1 | 1-3 | 1 |
| Answer this question if clinicians at your cancer program order at least five outpatient liquid biopsy tests (i.e., cell-free DNA) each year | NS | 3 | NS |
| Gaps or breakdowns in communication between pathologists and clinicians ordering outpatient liquid biopsy tests (i.e., cell-free DNA) and interpreting results | | | |

| BREAST | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--------------------|---------------|
| | Site 1 | Site 2 | Site 3 |
| Location | Topeka, KS | Greensboro, NC | Las Vegas, NV |
| Setting | Urban | Urban/ Suburban | Urban |
| Expertise and experience among pathologists who make a breast cancer diagnosis | NS | 2-3 | 3 |
| Quality and completeness of solid tumor pathology reports when a new cancer diagnosis is made; reports follow the College of American Pathologists (CAP) Cancer Protocol & Biomarker Templates | 3 | 2-3 | 3 |
| Gaps or breakdowns in communication (e.g., inaccurate, insufficient, or incomplete information) between pathologists and other members of the cancer care team when breast cancer biomarker tests are ordered | NS | 2-3 | 3 |
| Timeliness of obtaining breast cancer biomarker test results (less than 10 business days between sample receipt and reporting of all results) that may impact treatment decisions | 2 | 2-3 | 3 |
| Expertise and experience among pathologists who are interpreting hormone receptor status (ER/PR) and HER2 test results | 3 | 2-3 | NS |
| Availability and access (on-site or remote) to genetic counselors who can provide pre-test and post-test genetic counseling to patients with breast cancer who meet criteria for genetic testing for hereditary breast and ovarian cancer (HBOC) | NS | 2-3 | 1 |
| Genetic testing offered or performed in patients with breast cancer who meet criteria for genetic testing for hereditary breast and ovarian cancer (HBOC) | NS | 3 | NS |

| PROSTATE | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--------------------|---------------|
| | Site 1 | Site 2 | Site 3 |
| Location | Topeka, KS | Greensboro, NC | Las Vegas, NV |
| Setting | Urban | Urban/ Suburban | Urban |
| Expertise and experience among pathologists who make a prostate cancer diagnosis | 3 | 3 | NS |
| Quality and completeness of solid tumor pathology reports when a new cancer diagnosis is made; reports follow the College of American Pathologists (CAP) Cancer Protocol & Biomarker Templates | 3 | 3 | 3 |
| Gaps or breakdowns in communication (e.g., inaccurate, insufficient, or incomplete information) between pathologists and other members of the cancer care team when prostate cancer biomarker tests are ordered | NS | 3 | 3 |
| Timeliness of obtaining prostate cancer biomarker test results (less than 10 business days between sample receipt and reporting of all results) that may impact treatment decisions | NS | 2-3 | 3 |
| Availability and access (on-site or remote) to genetic counselors who can provide pre-test and post-test genetic counseling to patients with prostate cancer who meet criteria for genetic testing for hereditary prostate cancer | NS | 2-3 | 1 |
| Genetic testing offered or performed in patients with prostate cancer who meet criteria for genetic testing for hereditary prostate cancer | NS | 1-3 | NS |

| COLORECTAL | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--------------------|---------------|
| | Site 1 | Site 2 | Site 3 |
| Location | Topeka, KS | Greensboro, NC | Las Vegas, NV |
| Setting | Urban | Urban/ Suburban | Urban |
| Expertise and experience among pathologists who make a colorectal cancer diagnosis | 3 | 3 | 3 |
| Quality and completeness of solid tumor pathology reports when a new cancer diagnosis is made; reports follow the College of American Pathologists (CAP) Cancer Protocol & Biomarker Templates | 3 | 3 | 3 |
| Gaps or breakdowns in communication (e.g., inaccurate, insufficient, or incomplete information) between pathologists and other members of the cancer care team when colorectal cancer biomarker tests are ordered | NS | 2-3 | 3 |
| Timeliness of obtaining colorectal cancer biomarker test results (less than 10 business days between sample receipt and reporting of all results) that may impact treatment decisions | NS | 2-3 | 3 |
| The cancer program has policies for universal Mismatch Repair (MMR) or Microsatellite Instability (MSI) testing for all cases of colorectal cancer | NS | 3 | 3 |
| Availability and access (on-site or remote) to genetic counselors who can provide pre-test and post-test genetic counseling to patients with colorectal cancer who meet criteria for genetic testing for hereditary colorectal cancers | NS | 3 | 1 |
| Genetic testing offered or performed in patients with colorectal cancer who meet criteria for genetic testing for hereditary colorectal cancers | NS | 2-3 | NS |

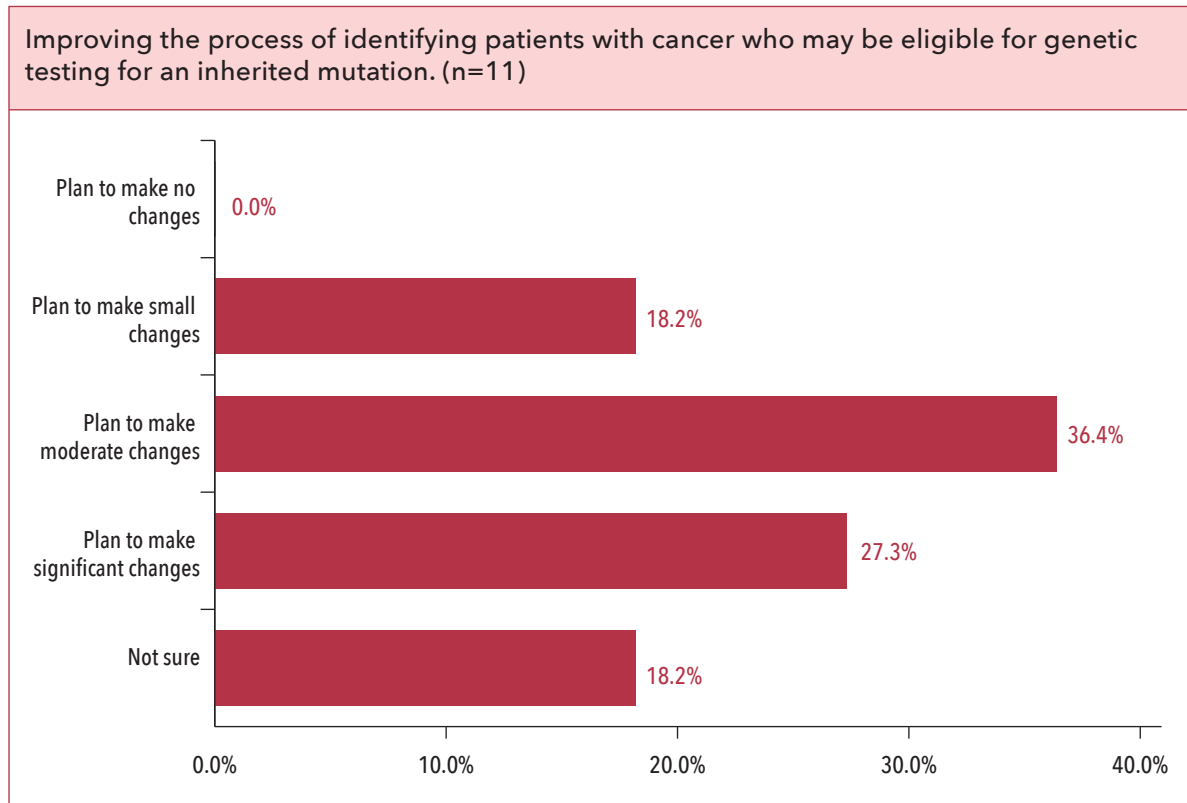
| HEMATOLOGIC MALIGNANCIES | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--------------------|---------------|
| | Site 1 | Site 2 | Site 3 |
| Location | Topeka, KS | Greensboro, NC | Las Vegas, NV |
| Setting | Urban | Urban/ Suburban | Urban |
| Expertise and experience among pathologists who make a hematologic malignancy diagnosis | NS | 2-3 | 3 |
| Gaps or breakdowns in communication (e.g., inaccurate, insufficient, or incomplete information) between pathologists and other members of the cancer care team when ancillary studies (e.g., flow cytometry, molecular diagnostics, etc.) for hematologic malignancies are ordered | NS | 2-3 | 2 |
| Timeliness (less than 10 business days between sample receipt and reporting of all results) of obtaining results for ancillary studies (e.g., flow cytometry, molecular diagnostics, etc.) that may impact treatment decisions | NS | 2-3 | 2 |

| LABORATORY PROCESS | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--------------------|---------------|
| | Site 1 | Site 2 | Site 3 |
| Location | Topeka, KS | Greensboro, NC | Las Vegas, NV |
| Setting | Urban | Urban/ Suburban | Urban |
| Pathology lab policies and procedures to ensure proper tissue handling for timely and accurate biomarker testing of biopsy samples | NS | 2-3 | 3 |
| Formalized process for regularly reviewing and updating policies and procedures to incorporate the appropriate use of new and novel tests (e.g., comprehensive genomic profiling) into clinical practice | 1 | 2-3 | 3 |
| Information technology (IT) resources and infrastructure within the lab to support pathology workflow, reporting, and communication with cancer clinicians | NS | 1-3 | 3 |
| Staffing resources for pathology lab practice management (e.g., handling insurance coverage, reimbursement, billing, etc.) | NS | 2-3 | NS |

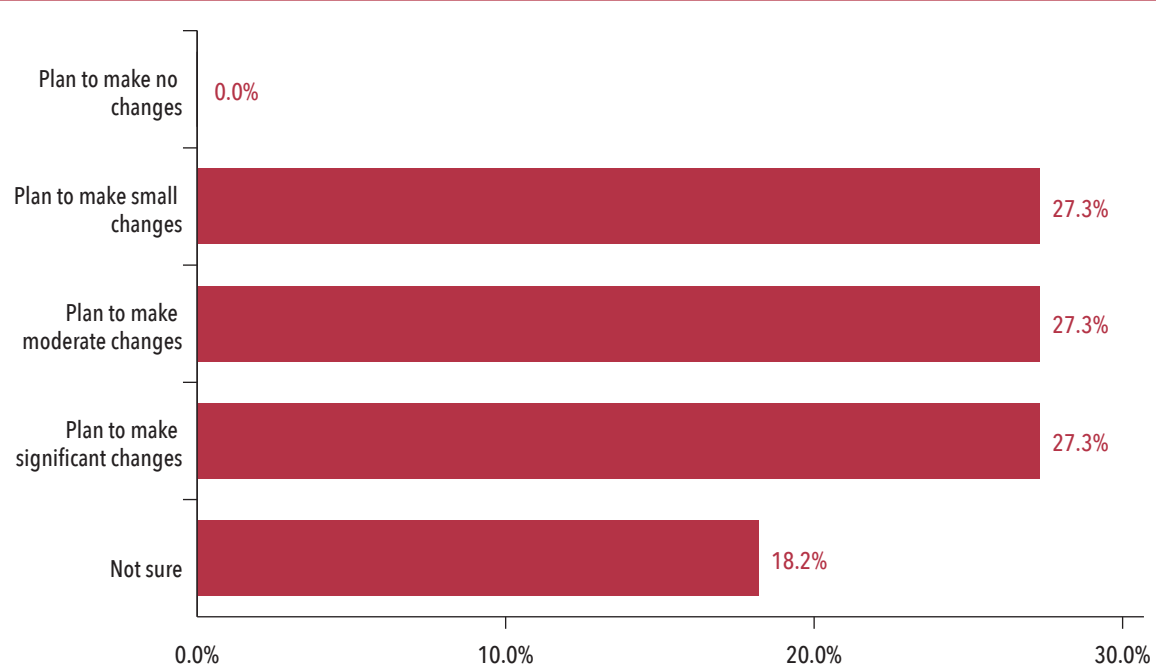
Post-Program Evaluation

N=12 (Topeka, KS = 5; Greensboro, NC = 2; Las Vegas, NV = 5)

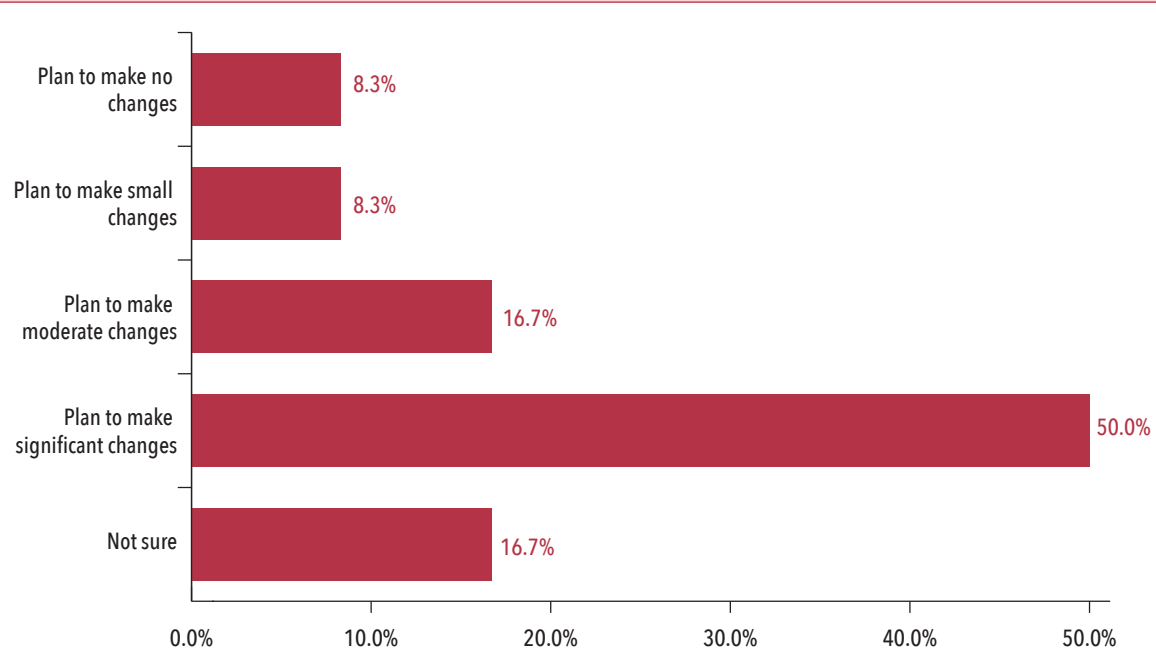
Please indicate whether you think your cancer program plans to make positive changes in the following areas:



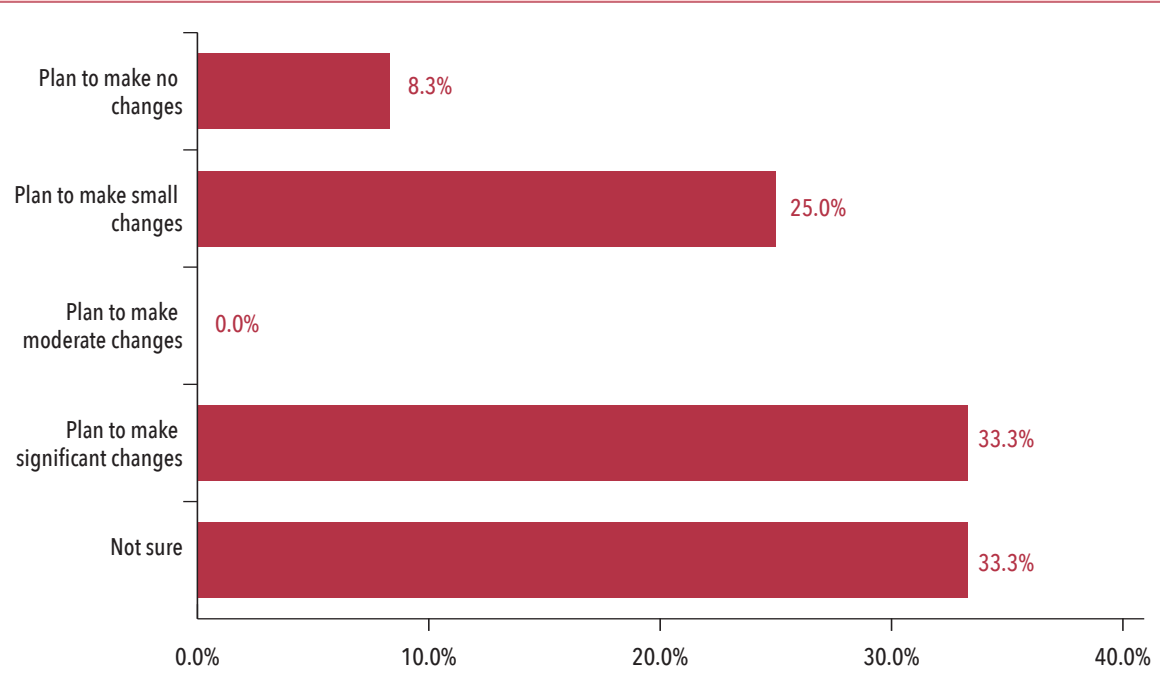
Improving the process of ordering biomarker testing and/or genetic testing for an inherited mutation for patients with cancer. (n=12)



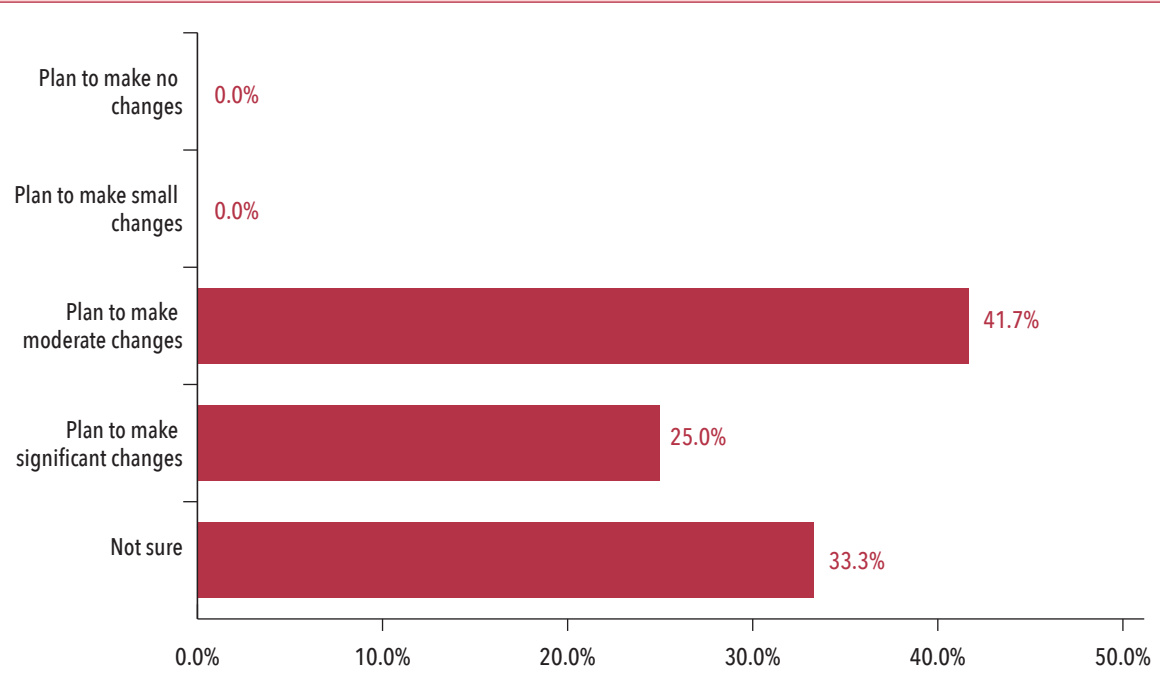
Improving how patients access genetic counselors who can provide pre-test and/or post-test genetic counseling. (n=12)



Improving how patients are notified if/when their genetic test results are reclassified. (n=12)



Incorporating more discussions during tumor board meetings about genetic testing for an inherited mutation. (n=12)



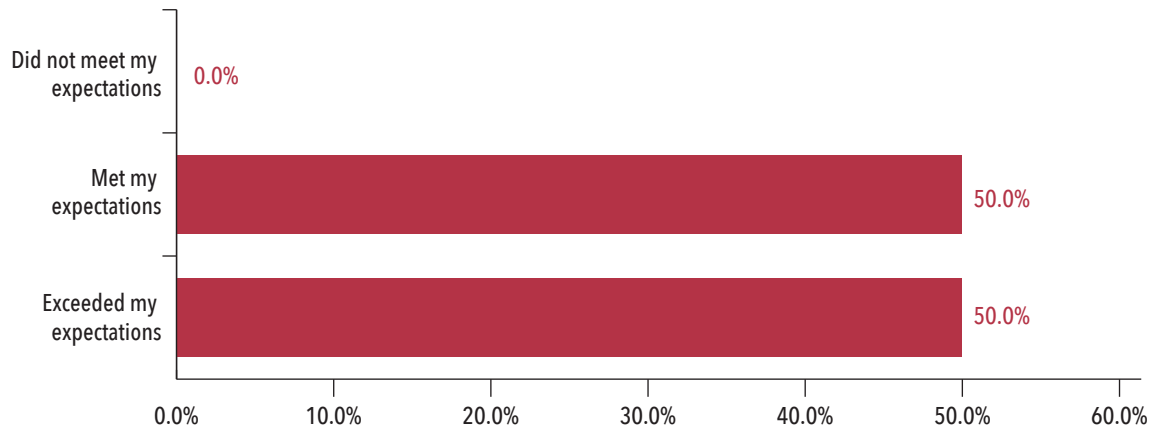
What was your biggest takeaway from the workshop?

- Some of our oncologists want to learn more about how their patients could access genetic counseling.
- Incorporating the urological services team to utilize biomarker testing.
- Indications leading up to cancer types and testing.
- This is a changing landscape, and it is important to recognize the impact of genetic/biomarker testing on patients. This is especially true now that test results and pathology reports go directly to patients.
- The discussion with the interdisciplinary team as a whole was great. The different perspectives between departments and providers were very insightful.
- Need for more universal consideration of genetic screening and patient counseling.
- That I don't know enough about genetics! There is always room to learn more.
- We can do better with respect to genetic testing and biomarker discussions with patients and among disciplines/consults.
- Learned a lot about the different tests and the significance of treatment options based on genetic abnormalities.

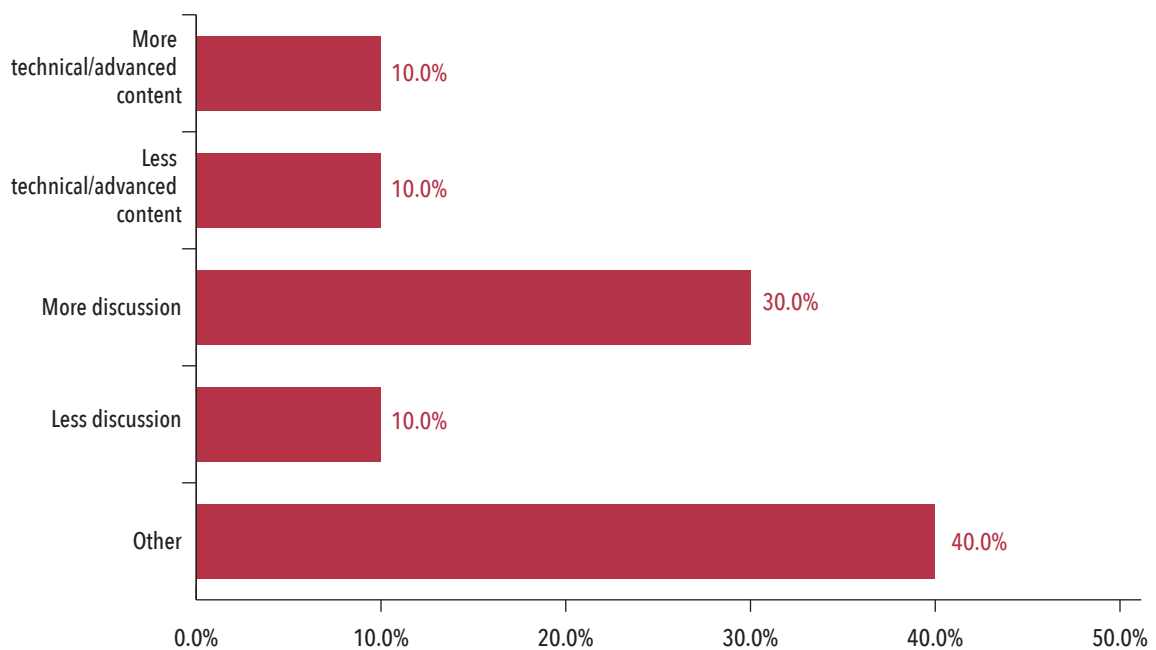
What other positive changes do you anticipate your cancer program may implement as a result of the workshop discussion?

- Pathology: We can use the term "biomarker testing" for tumors and reserve "genetic testing" for germline testing. We can be cognizant when our biomarker testing detects possible germline mutations and notify the clinician.
- I really think this workshop opened up everyone's eyes about the different processes/procedures available. With this updated information I think we'll be able to streamline our genetic testing process even further.
- We are looking into the MSI/IHC testing and reflex testing for BRAF and Methylation by our pathology lab as we felt that was one improvement we could work on.
- Hoping to offer those more resources to genetic testing if available.
- Not certain but plan to review in our committee(s).
- More consistent communication with genetic counseling in nearby practices.
- The nurse navigator and I will be meeting with the genetics counselor at comprehensive cancer to make them more of a part of our team.

Please provide an overall rating for the workshop: (n=12)



For future workshops, would you prefer: (Select all that apply.)

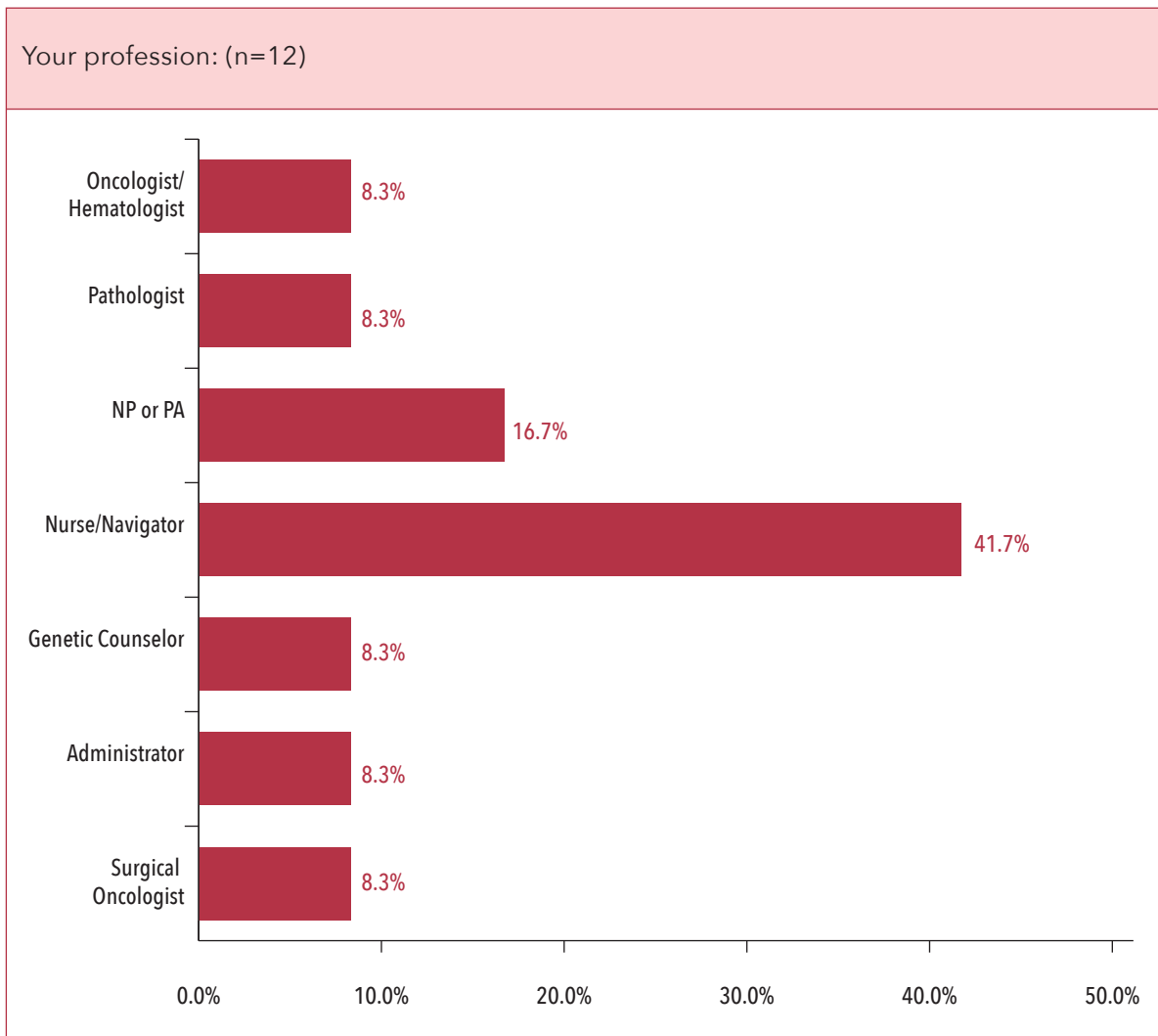


Other:

- Was a good blend of both.
- I would really like to understand how our genetics program compares with other programs, and receive specific feedback on action items we could take in order to make improvements.
- Hear how other cancer centers our size are tackling these issues.

Do you have any other comments you would like to provide about the workshop?

- I felt that this was informative. Overall, I felt that my take-away from this was that the genetics program was doing much of what you all were discussing.
- It was hard to see the slides as I was connected on my phone. I would have loved to have received a copy of the slide deck to be able to print.
- The workshop was very technically driven and I would like to see more discussion around support for patients.





A publication from the ACCC education program, "Precision Medicine: Integration of Pathology with the Cancer Care Team." Learn more at acc-cancer.org/pathology.

The **Association of Community Cancer Centers (ACCC)** is the leading education and advocacy organization for the cancer care community. Founded in 1974, ACCC is a powerful network of 28,000 multidisciplinary practitioners from 2,100 hospitals and practices nationwide. As advances in cancer screening and diagnosis, treatment options, and care delivery models continue to evolve—so has ACCC—adapting its resources to meet the changing needs of the entire oncology care team. For more information, visit acc-cancer.org. Follow us on social media; read our blog, ACCCBuzz; tune in to our CANCER BUZZ podcast; and view our CANCER BUZZ TV channel.

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