

Molecular Testing in the Community Oncology Setting

THE EVOLUTION OF PERSONALIZED MEDICINE IS HAVING AN IMPACT on oncology patient care—both diagnostically and therapeutically. The past several years have seen an increased use of genetic markers and molecular testing in oncology clinical decision making. While

these tests have been accepted into general practice guidelines once clinical utility is proven, adoption and use of molecular tests in the community setting have been slower and somewhat fragmented. Understanding the challenges around molecular testing for community-based providers is important to both practicing clinicians and the patients they serve.

ACCC Established the Molecular Testing in the Community Oncology Setting project to:

- Understand the current molecular testing landscape in the community setting from a multidisciplinary perspective, including barriers to use of molecular testing
- Identify a variety of community-based cancer programs that are succeeding in implementing molecular testing, thereby improving patient care
- Develop case studies that exemplify key success factors and effective practices in the implementation of molecular testing.

Why This Project Now?

- Growth in use of molecular biomarkers in clinical decision making
- Increase in number and complexity of molecular tests (both diagnostic and therapeutic) for oncology
- An estimated 2,000 molecular tests (oncology and non-oncology) are currently available and about 1,000 new tests are developed each year
- New oncology drugs with companion diagnostic tests approved by the FDA
- No one-size-fits-all approach to integration or use of molecular tests in the community setting.

What We Did

In the spring of 2012, ACCC's Center for Provider Education established an Advisory Panel to help guide the project. With the Advisory Panel's input and oversight, the consulting firm of Health Equity Associates developed two survey instruments to inform an environmental scan of molecular testing in the community setting. Each survey addressed adoption of molecular testing with a focus on three leading disease sites: breast cancer, lung cancer, and melanoma. The two online surveys, which were promoted to ACCC members via email, were conducted during the summer of 2012. Health Equity Associates provided survey analysis, conducted follow-up interviews, and developed four case studies of effective practices through September 2012. Preliminary project results were reported at the 29th ACCC National Oncology Conference in October 2012. The project final report including an annotated bibliography and case studies is available to ACCC members at www.accc-cancer.org/moleculartesting.

Members of the Advisory Panel include: Samuel Caughron, MD, FACP; William J. Laffey, MBA; Zaven R. Norigian, Jr., PharmD, BCOP; Randall A. Oyer, MD; Cary Presant, MD; Gail W. Probst, RN, MS, ANP, OCN, AOCN, NE-BC; Lonnie K. Wen, PhD (sponsor delegate); and John M. Yelcick, MD.

Survey Overview

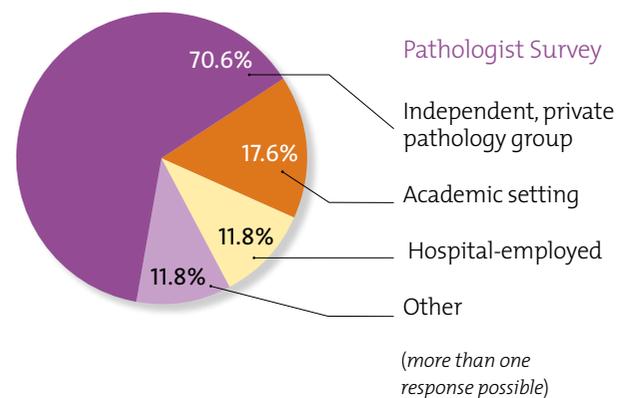
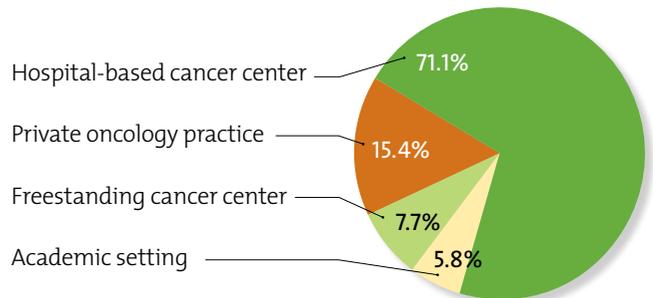
Each survey instrument was designed to further an understanding of current utilization of molecular testing in the community setting, as well as any barriers or effective practices in integration of molecular tests. The multidisciplinary survey targeted oncologists, administrators, nurses, and pharmacists. Fifty-two cancer programs submitted responses, representing cancer programs in more than 25 states. Although similar to the multidisciplinary survey, the pathologist survey included some additional discipline-specific questions. Seventeen pathologists submitted responses. For both surveys, questions explored current practices, policies, and procedures; testing processes; reimbursement; and administrative issues.

Survey Findings

The majority of multidisciplinary respondents were hospital-based cancer programs. Of these, 71.9% reported that cancer programs work with a hospital-employed pathology department. Most pathologist survey respondents (70.6%) were associated with an independent, private pathology group.

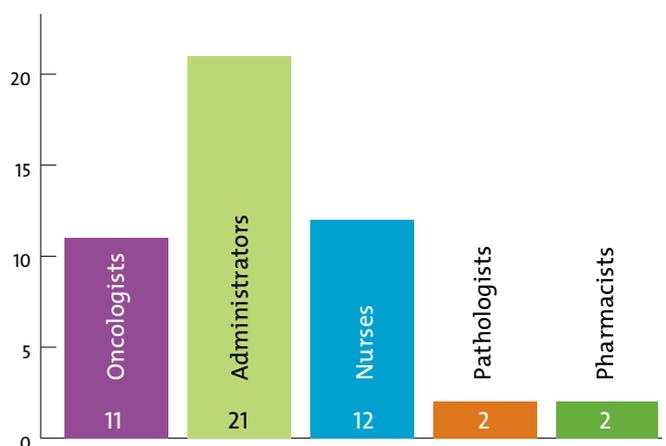
Respondents by Setting of Care

Multidisciplinary Survey



Multidisciplinary Respondents by Role

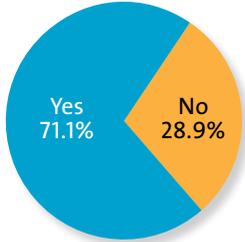
(by number of respondents)



Is a Policy or Process in Place to Adopt New Molecular Tests?

Nearly three-quarters of multidisciplinary respondents (71.1%) have a policy in place to consider adoption of new molecular tests.

Multidisciplinary Survey



Two-thirds of pathologists surveyed (62.5%) indicated their facility has administrative guidelines, policies, or procedures regarding use of molecular tests.

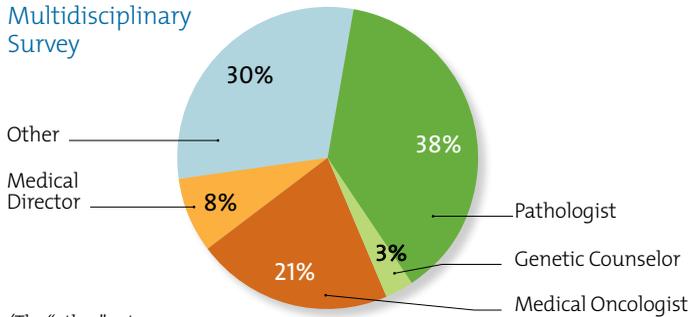
With respect to criteria for adoption of new molecular tests (i.e., identified clinical criteria, clinical utility, evidence-based criteria), 41.2% reported they have criteria while the same number have not yet established such criteria. The remaining 17.6% indicated that they intended to implement criteria in the next year.



Who Takes the Lead in Adoption Policy/Process?

According to 58.8% of pathologist respondents, oncologists provide primary guidance on biomarker testing, while 38% of multidisciplinary respondents reported that pathologists take the lead.

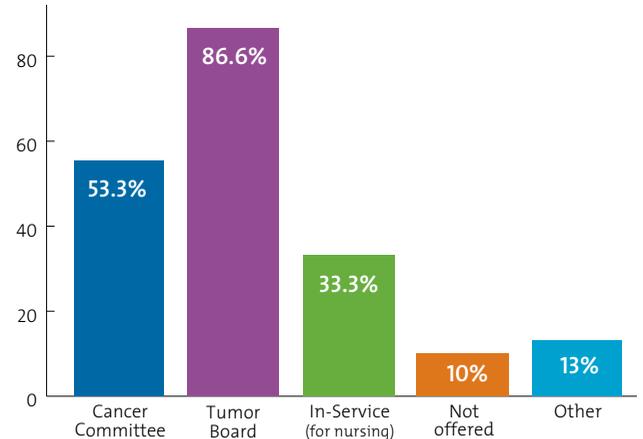
Multidisciplinary Survey



(The "other" category included pharmacists, patient navigators, and administrators.)

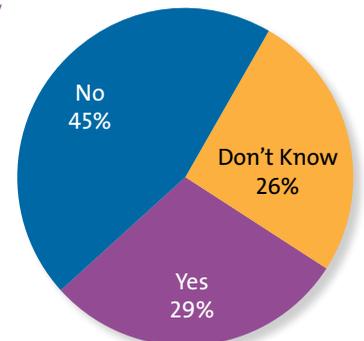
Where is Education on Molecular Testing Taking Place?

Multidisciplinary Survey



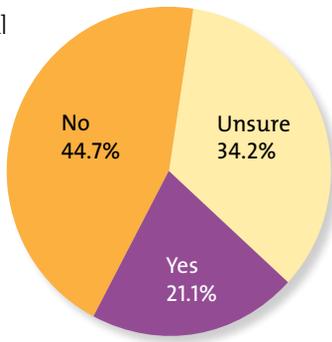
Does Your Program Have a QI/PI Process in Place for Molecular Testing?

Multidisciplinary Survey



Policy on Obtaining Additional Tissue

Most multidisciplinary respondents report no policy/procedure on obtaining additional tissue for retesting.

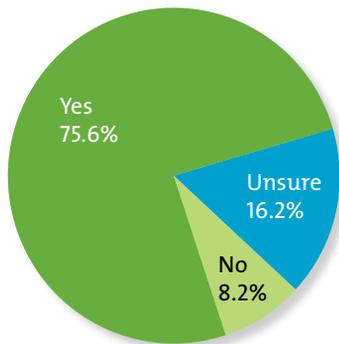


Molecular Testing in Standard of Care by Disease Site

Breast cancer was most likely to have required molecular oncology testing incorporated into the cancer program's standard of care as reported by 93.3% of multidisciplinary respondents. Six in ten respondents stated molecular testing was built into lung cancer standard of care, about the same as that reported for melanoma. Nearly 41% reported that molecular testing was included under colon cancer standard of care.

Use of Guidelines

Most multidisciplinary respondents (75.6%) report following guidelines on use of molecular testing.

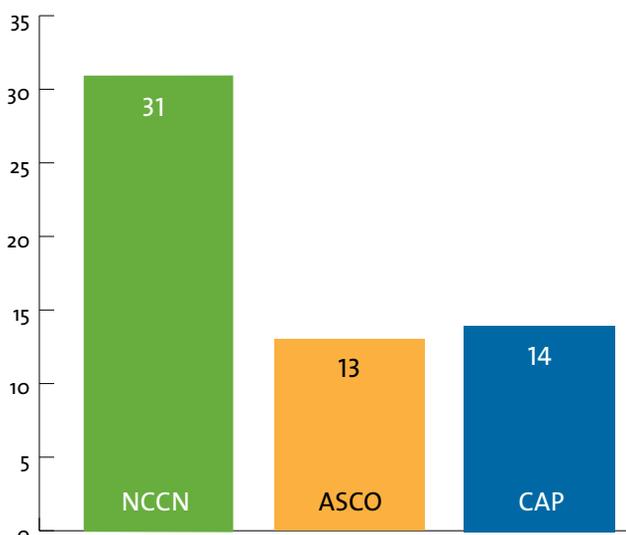


“The biggest challenge is grappling with the pace of change. It’s the speed of change, and everybody is saying, ‘How on earth are we going to choose from this massive menu and how on earth are we going to pay for any of it? It’s all so fancy and does it really work and does it help us do anything at all for the patient?’ But at the same time, we know this is going to grow. If you think about personalized medicine, then there is no end to the number of tests that you could perform.”

—Focus group participant

Guidelines Most Used

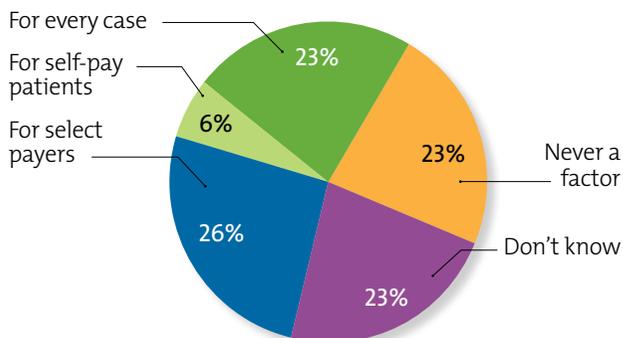
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Impact of Cost of Testing

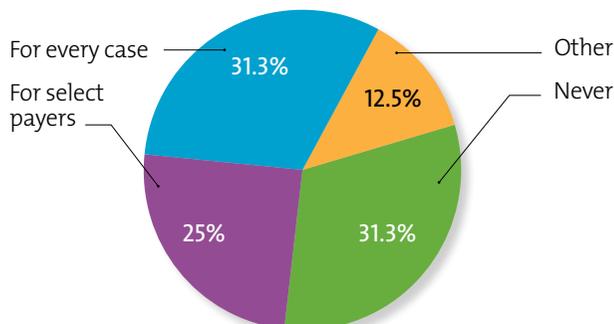
Multidisciplinary Survey

How often does cost of biomarker testing impact whether or not the test is ordered/performed?



Pathologist Survey

How often does cost of biomarker testing impact whether or not the test is ordered/performed?



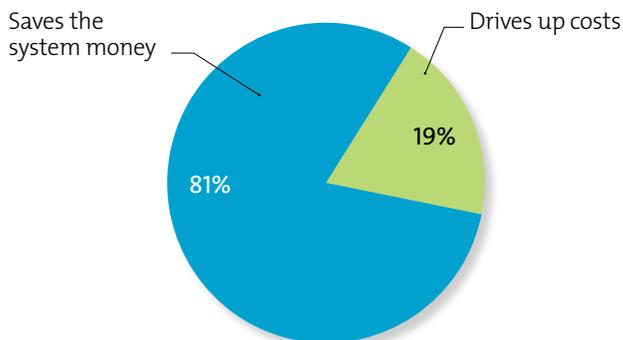
Bringing New Tests In House

Just over one-third of multidisciplinary respondents said they intend to bring new molecular tests in house within six months, while 35.3% of pathologists reported they planned to bring new molecular tests in house within the same time frame.

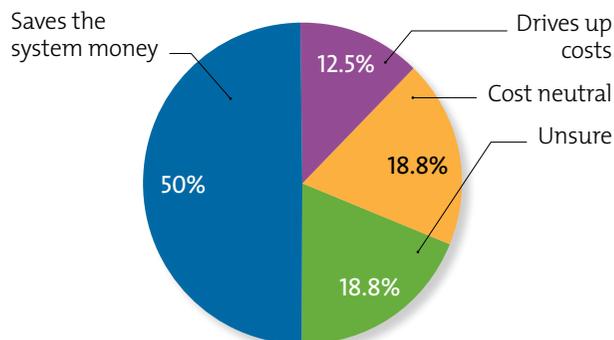


Most Respondents Believe Molecular Testing will Save the Health System Money

Multidisciplinary Survey



Pathologist Survey



For more on this project, visit www.accc-cancer.org/moleculartesting

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Effective Practices for Integrating Molecular Testing

Project findings identified the following key effective practices in integrating molecular testing in the community setting:

1. Physician champions

- Pathologist and medical oncologist champions for molecular testing
- Strong collaborative relationship between disciplines
- Willingness to evaluate and discuss a test's clinical utility and predictive demand

2. Administrative support

- Resources to perform comparative analysis
- Support for significant resources up front with returns to follow later
- Assumption of risk that some tests may be a loss leader for several months

3. Multidisciplinary communication

- Early involvement of entire multidisciplinary team
- Consistent discussion of molecular testing at tumor board, cancer committee, quality committee

4. Genetic counseling and care coordination

- Genetic counselor services are available
- Staff dedicated to coordinating care across settings, i.e., patient navigators

5. Ongoing staff education on molecular testing

- Cancer conferences
- Tumor boards
- Journal clubs
- In-service trainings

Barriers to Use of Molecular Testing

- Lack of interest by members of the physician team (pathologists and/or specialty physicians) to transition to individualized care
- Lack of collaborative relationship between specialty physicians
- Need for significant investment; competing capital priorities
- Unwillingness of administration to take risks and invest time, money, and staff up front

Strategies to Overcome Barriers

- Using peer pressure to elevate non-utilizers (physician to physician)
- Discontinuing contracts of physician partners unwilling to elevate the standard of practice
- Having lead pathologists and oncologists present evidence of necessity to keep current with clinical offerings of competing health systems to prevent loss of downstream revenue
- Implementing multidisciplinary strategic planning processes that focus on developing team collaboration and communication strategies

Challenges Ahead

- Achieving buy-in from all physicians and consensus on program needs
- Competing capital needs—budget constraints, prioritizing all new capital investments
- Keeping up with the pace of change

