ASSOCIATION OF COMMUNITY CANCER CENTERS

INTEGRATION OF PATHOLOGY IN ONCOLOGY CARE

LEADERSHIP SUMMIT PROCEEDINGS

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ACCC
Association of Community Cancer Centers

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Comments expressed by summit participants are their own and do not represent the opinions of the Association of Community Cancer Centers or the institutions with which the participant is affiliated.

Summit Objectives

Develop a list of opportunities to improve the integration of pathology into cancer care in community cancer centers in the following areas:

- Cancer biomarker testing and molecular pathology
- Cancer diagnosis and treatment discussions/decisions
- Policy and reimbursement

Identify priority areas for immediate action that could lead to improvement within the next year.

Executive Summary

The Association of Community Cancer Centers (ACCC), along with partners the Association for Molecular Pathology (AMP), the American Society for Clinical Pathology (ASCP), and the College of American Pathologists (CAP) convened the **Integration of Pathology in Oncology Care Leadership Summit** in July 2018. The impetus for the meeting was to gain insight from a wide variety of stakeholders on how to better align advances in molecular pathology with the current infrastructure of cancer care delivery. Participants, including oncologists, pharmacists, pathologists, genetic counselors, social workers, nurses, surgeons, service line leaders, and others, from hospitals, academic and community cancer programs, payer entities, patient advocacy groups, labs and diagnostic companies, and technology platforms came together for this vital conversation.

The discussion focused primarily on three topic areas: the state of cancer biomarker testing and molecular pathology, the diagnosis and treatment decision-making process, and policy and

reimbursement issues. Through panel discussions, breakout group conversations, and interactive presentations, participants shared perspectives on how pathology is currently integrated with the multidisciplinary cancer care team and what opportunities exist to improve on the status quo.

Through a consensus-driven process, summit participants identified seven opportunities as the most feasible and impactful for achieving closer integration of pathology with the cancer team:

- Empower pathologists and the oncology care team for culture change
- Standardize the testing order process
- Improve specimen management
- Generate "one pathology report"
- Optimize virtual tumor boards
- Strengthen the alliance between pathology and genetic counseling
- Educate and empower patients

With the exponential growth in our knowledge and understanding of cancer, improved communication and collaboration between oncology and pathology is critical. The Integration of Pathology in Oncology Care Leadership Summit has identified actionable next steps for needed change in the integration of pathology with the oncology team across the care continuum. Through thoughtful discourse, participants clarified some approaches to address educational, technological, cultural, and communicative gaps between pathology and oncology. The proceedings that follow provide a description of the summit discussion and details on the seven action steps identified.

Introduction

The role of pathology in the diagnosis and management of cancer has changed in the era of precision medicine and rapidly progressing cancer therapies. Continuing advances in molecular biology, immuno-oncology, and targeted therapies require greater integration and coordination of pathology with the multidisciplinary cancer care team.

On July 31, 2018, the Association of Community Cancer Centers (ACCC), along with partners the Association for Molecular Pathology (AMP), the American Society for Clinical Pathology (ASCP), and the College of American Pathologists (CAP) held the Integration of Pathology in Oncology Care Leadership Summit in Washington, D.C. More than 60 multidisciplinary stakeholders participated from hospitals, academic and community cancer programs, payer entities, patient advocacy groups, labs and diagnostic companies, and technology platforms. Participants came together to discuss how pathology fits within the current cancer care continuum across various settings and to consider opportunities to improve the integration of pathology into cancer care in community oncology programs with a focus on cancer biomarker testing and molecular pathology; cancer diagnosis and treatment discussions/decisions; and policy and reimbursement. Summit participants were tasked with identifying and achieving consensus around high-priority areas in which immediate action steps could be taken that would result in improvement within the next year.

The summit discussion focused on three topic areas: the state of cancer biomarker testing and molecular pathology, the diagnosis and treatment decision-making process, and policy and reimbursement issues. Through panel discussions, breakout group conversations, and interactive

presentations, participants shared perspectives on the current state of pathology integration within cancer care and identified potential opportunity areas where improvement on the status quo could be made. (View summit agenda in Appendix A.)

As a group, summit participants reached consensus on seven of the most feasible and impactful opportunities for improving the integration of pathology with the cancer team and identified next steps for taking action. What follows is a summary of the summit discussion of the current landscape, what improvements could be made, how the identified action items could help improve integration of pathology into oncology, and what actions could be taken in the short term.

"One Change" Challenge

Summit facilitator Robert Mittman opened the meeting by asking each participant to name one change that would lead to closer integration between pathology and the multidisciplinary cancer care team. Responses in this introductory lightning round fell into four main categories:

Change the Pathologist's Role

- Empower pathologists to play a consultative role
- Position pathologists as expert advisors rather than merely service providers to oncology
- Support pathologists to become educators on molecular biomarker testing and applicability of testing results for the cancer care team
- Position pathologists to serve as leaders in the cancer care team

Provide More Training and Education

- Real-time education to stay current with the latest information on biomarkers and molecular tests
- Virtual tumor boards
- More training for pathologists—"today all pathologists should consider themselves molecular pathologists"

Standardize Processes and Operations

- Assess the distribution of expertise on molecular biomarkers, biomarker testing, specimen collection and preparation, and interpretation of testing results
- Clarify and streamline processes, diagnostic protocols, role of biomarkers
- Leverage technology for data analysis, communication, collaboration
- Obtain reimbursement for new roles
- Apply data science, make results more usable, house results in discrete data fields

Increase Communication and Engagement

- Improve patient understanding of molecular biomarkers, testing, and how results can inform care treatment decision-making
- Support communication across health system silos, across disciplines, between pathology and the cancer care team, and with payers

- Better define quality; order the right tests, for the right patients, at the right time—based on evidence
- Strengthen physician engagement, professionalism, leadership, change management, organizational culture
- Educate policymakers about the importance of these tests and barriers due to policy lagging behind advances in diagnosis and treatment for cancer

In preparation for the summit, in the spring of 2018 ACCC, together with partner organizations Association for Molecular Pathology, American Society for Clinical Pathology, and the College of American Pathologists, conducted a survey to gain insight into the current landscape of pathology, specific to the integration with oncology.

This survey received over 600 responses. Seventy-eight percent of survey respondents reported that pathologists attend the majority of their organization's tumor boards;[1] 37 percent reported that pathologists recommend treatment options during these discussions.[2] However, only 14 percent of respondents reported that pathologists have one-on-one conversations with medical oncologists to discuss treatment recommendations.[2] Further, less than half of respondents (43 percent) said that pathologists are authorized to order any type of biomarker test; while 34 percent reported that pathologists have authority to order only certain tests, and 5 percent reported that pathologists cannot order any testing.[3] Survey results were then incorporated into an environmental scan prepared as pre-reading for summit participants.

In addition to survey findings, the scan included peer-reviewed articles and conference findings from multiple sources and, as such, is reflective of the current level of pathologist engagement in the discussion and decision-making processes behind cancer diagnosis and treatment.

Access the survey highlights and environmental scan at accc-cancer.org/pathology.

Cancer Biomarker Testing and Molecular Pathology: Current Practices

A facilitated panel discussion began the summit conversation. Panelists Tim Allen, MD, JD, FACP, Professor and Department Chair, Pathology, *University of Mississippi*; Pablo Gutman, MD, MBA, Medical Director and Department Chair, Pathology, Cancer Institute, *Holy Cross*; and Mohamed K. Mohamed, MD, PhD, Director, Thoracic Oncology Program, Hematologist/Oncologist, *Cone Health System,* shared the processes at their respective institutions for selecting and ordering testing, along with challenges and effective practices in integration of molecular testing.

The panelists provided perspectives from an academic medical setting, a health system, and a pathologist medical director in the community setting. The discussion reflected the variation that currently exists in how tests are selected, who orders the testing, where the testing is performed (i.e., in-house or at an outside lab), who first receives the test results, and, in some instances, who interprets the test results. Decision-makers on test selection range from standing committees at larger academic institutions to more ad hoc processes at smaller sites, where the test selection is under the purview of one individual, e.g., medical director.

Panelists described scenarios in which biomarker tests may be selected and ordered by different providers, often based on the volume of tests requested. So, for example, medical oncologists may

order biomarker testing for lung cancer and pathology may order for established, routine tests (e.g., breast cancer). Testing orders from medical oncologists may be insufficient in diagnosing a cancer; in some settings, pathologists may not be permitted to order certain tests due to interpretations of the Stark Law.

Specialists performing biopsies may not be attuned to specific requirements for specimen collection, panelists noted. Lack of standardization in the test ordering process can lead to confusion surrounding the communication pathways for test ordering, repeated biopsies and testing, and delays in test results, ultimately hindering the cancer team from delivering the best possible care for patients.

Panelists and participants concurred on the need to standardize high-volume requests, adjust processes as the evidence evolves around biomarkers and testing, and to have clear, consistent processes in place for test selection and ordering. Establishing formal agreements and policies/procedures is seen as needed step.

Tissue collection, preparation, and sufficiency of sample size—all continue to present challenges, panelists agreed. In current practice, patients may need to get re-biopsied because those responsible for tissue collection may not be aware of the pathologist's needs across cancer types, tumor sites, and specific tests. Testing (and treatment options) should not be omitted due to a lack of quality tissue to work with, and patients should not have to go through multiple procedures due to an inadequate tissue sample. One of the most impactful things providers can do, one participant commented, is to treat every cell of each patient as "precious."

The College of American Pathologists (CAP) has "work to do on guidelines to address the multidisciplinary team approach," noted the panelists. Pathologists are asked to "do more and more with less and less" tissue. To manage the demand [for tissue] requires constant communication with interventional radiology, as well as well-trained technicians, commented one panelist. Another panelist added that even with well-trained staff, there are still times when his lung program does not have enough tissue. Standards and guidance on which tests to perform in order to make best use of tissue specimens are much needed, the panel agreed.

While all three panelists send some molecular testing to outside labs—there is variation here, too, and economics play a role. The academic program plans to bring cost-effective tests in-house. But for community hospitals setting up their own molecular pathology lab might not be an option. Although one panelist reported sending all his testing to an outside lab because he trusts the lab's quality, the turnaround time—which can be two to three weeks—is a frustration.

In the ACCC survey 56 percent of respondents indicated that they have molecular pathologists and 24 percent reported that they have a cancer genetics team.[4] According to survey results, the most common type of biomarker testing performed in-house is breast cancer (46 percent), and across all respondents, 13-25 percent report using a combination of in-house and outside lab testing.[5]

Variation extends to the utilization of next generation sequencing (NGS) testing. One panelist sends more than 90 percent of his samples for NGS testing; another panelist reported rarely ordering NGS testing due to cost. The third panelist noted that NGS is an evolving area. "Quality has to be number one on everyone's agenda, then economics," he said.

Who is interpreting the molecular pathology test results? In discussing this question, panelists and summit participants reflected lack of consistency in terms of who is interpreting test results at their programs. One institution is trying to establish a process where the tests will go directly to the pathologist most experienced in molecular pathology. While the general sense among summit participants was that the testing results should be sent to pathology first, some labs send results directly to the ordering oncologist. In some programs, oncologists have begun to subspecialize and are trained to interpret the test results. Yet at other programs, how much of the pathology report is interpreted by the pathologist is dependent on the diagnosis.

The discussion touched briefly on reimbursement for biomarker testing and the need for greater involvement of pathology in educating the multidisciplinary cancer care team on testing and how results may impact diagnosis and treatment planning. However, pathologists are paid based on RVUs (volume) and thus are not incentivized to expand their role by integrating more closely with the multidisciplinary care team. "We are [still] living in a world in which payment is based on procedures. The opportunity to meet is how can we take care of patients in ways that are not procedure-based and still be paid appropriately," said one panelist.

Breakout Session: Opportunities in Biomarker Testing and Molecular Pathology

Following the facilitated panel discussion, summit participants divided into working groups to build on the previous conversation and identify opportunities in biomarker testing and improvements in integration of molecular pathology with oncology that stand to have the greatest impact for cancer care in the community. For the most part, the working group discussions centered around standards and standardization, education, communication, and reimbursement. The summit participants re-convened, and each working group reported on the opportunities identified. Key takeaways from the groups are highlighted below.

Break down silos. Tumor molecular testing is eroding the boundaries between oncology and other fields, a participant noted. This presents an opportunity/necessity to expand the cancer care team to involve primary care physicians and other providers to diagnose, treat, and identify potential comorbidities or disease states. Describing the current siloed relationship between oncology and pathology, one participant employed a wall metaphor. The testing order is "thrown over the wall" to pathology by the oncologist, and pathology throws the results back over the wall to oncology.

Standardize the test ordering process based on evidence. A large array of tests is available, commented a participant. Some of these are actionable; some are not. Suggestions were made to standardize the test ordering process with clinical pathways and simplify the ordering process for patients.

Leverage EHRs for workflow integration. EHRs could house high-quality evidence-based information from the point of tissue acquisition to defining high-quality testing, and even contain the letters required to go to all providers involved in a patient's care. Participants stressed the need for discrete data fields within the EHR that would auto-populate with information. Development of a standardized EHR that incorporates clinical information and lab information could, ideally, produce integrated reports

with uniform standards for data elements in the EHR and LIS (laboratory information system) that includes a database of all the patient's testing and results.

Engage CAP to help pathologists "own" this area. Advocate for culture change so that pathologists are more engaged and involved in helping others understand molecular pathology, molecular biomarker testing, and the actionable information from a test.

Prepare and empower pathologists for culture change. Empower pathologists with a more central role in cancer care, including all the way to the patient. For closer integration between pathology and oncology, pathologists need to assume an active, leadership position in multidisciplinary tumor boards. Pathologists in the community need education and molecular training. Provide communication skills training to help prepare pathologists for this leadership role and to become patient advocates for evidence-based use of appropriate biomarker testing to help patients better understand the role of testing in diagnosis and treatment planning. Currently, there is little advocacy for patients related to the cost of testing.

Activate pathways to include patient engagement from the start to understand the implication of somatic and germline mutation.

Create one pathology report that is multidimensional and longitudinal. Integrate AI, EMR, query, financial support, and disparity information. The report should reflect time and continuity of patient care.

Accelerate the cycle for guidelines release/updates to meet the pace of updates to NCCN compendia.

Measure effectiveness of guidelines. Encourage stakeholders to perform regional assessment of variability in ordering patterns and adherence to guidelines.

Engage non-traditional stakeholders, business partners and payers, to accelerate guideline incorporation into the multidisciplinary care approach.

Provide context. Having patient-specific clinical context aids pathologists in test interpretation. At the same time, oncologists need context on molecular testing so that they have a clearer understanding of the appropriate test(s) to order. Further, patients need context so that they understand why the test is being ordered and how the results will impact treatment planning. In ACCC's survey when asked about the types of patient health records their pathologists can directly access, 38 percent of respondents answered all outpatient medical oncology, while 26 percent responded some outpatient medical oncology, and 62 percent reported they could access all inpatient records.[6]

Acknowledge and address reimbursement issues. If a program is incorporating diagnostic protocols, ensure that patients are aware of the cost or that the program is able to cover the cost.

Tissue Acquisition and Handling

- Standardize training for specimen collection and management. Provide education for radiologists, pulmonologists, surgeons, and others on the requirements for tissue collection and preservation. Educate across multiple disciplines that may obtain tissue. Identify best practices and share with the wider community.
- Coordinate companion diagnostic tests and their coverage criteria.

- Engage non-traditional stakeholders, business partners, and payers to accelerate guideline integration into the multidisciplinary approach. Coordinate these standards among disciplines.
- Create a dashboard for patient specimen.
- Accelerate the CAP guidelines process to meet the pace of NCCN compendia updates.
- Provide clinical decision support. One participant commented that defining what makes a test good and how to apply the results of a test are two difference things. For example, you can't know a patient's performance status from pathology report.

Cancer Diagnosis and Treatment Discussion/Decisions

As one summit participant said, "Tumor board is 'ground zero' for decision-making." However, pathologists are not reimbursed for attending tumor board. According to summit participants, pathologists are not incentivized to take a greater role in tumor board. In the ACCC survey less than half (37 percent) of respondents reported that "pathologists occasionally or frequently recommend treatment options during tumor board discussions."[7] In breakout working groups, summit participants brainstormed potential opportunities for closer integration between oncology and pathology in cancer diagnosis and treatment discussions and decision-making. Opportunities identified include:

Develop a diagnostic management team conference. "Moving from the tumor board of a bygone era to real-time tumor boards and getting paid for it." The envisioned virtual conference would be available to any interested providers as well as the patient and family members. Suggestions were to incentivize payers to reimburse for the conference, and to engage accrediting bodies to envision this conference as a tumor board. However, a barrier can be case volume, commented a participant, asking whether this conference should be limited to high-complexity cases.

For a diagnostic management conference, pathologists could leverage digital tools to join in the conversation and also connect the decision to outcomes. Further, it would increase patient satisfaction by having the team answering any questions. As one participant who is also a cancer survivor commented, the conference would help smooth "the roller coaster of the care experience and help patients/families manage the information overload." Show the value of the tumor board through data collection that documents value.

Facilitate electronic, bidirectional communication between pathologist and oncology provider at all times. Most pathology is conducted off-site by pathology practices, commented one attendee. By leveraging technology the pathology practice can get the information it needs and return information to the provider. The recommendation is for a practice-setting agnostic solution that would cover all sites of care. Everyone needs access to the patient records and needs to be on the same page, noted another participant.

Train pathologist in team-oriented skills. CAP and other organizations could develop non-clinical leadership and education materials.

Measure and incentivize pathologist communications. Currently pathologists are reimbursed for RVUs and are de-incentivized to participate in these activities. For quality standards that impact reimbursement, include pathology metrics and how integrated the pathologist is into the cancer care team.

Create pathology fellowships in oncology. Dermatopathologists and neuropathologists are existing models of pathologists who interact as part of an integrated team.

Centralize biomarker testing model in the community setting. Currently tests are sent out to various labs and come back at various times. Have results sent to the pathologist first; this will lead to better integration.

Improve patient education and increase empowerment. Create a pathology report that patients can understand; make patients aware of why testing is important. Design the report so that it can be used in shared decision-making.

Address the issue regionally. To promote standardization across the region, create regionally based, multi-institution tumor boards.

Develop new "personalized oncology" subspecialty. Moffitt Cancer Center is already working with this model, commented a participant.

Have pathologists as principal investigators (PIs) on clinical trials. As the design of clinical trials evolves with increasing focus on molecular biomarkers both in diagnosing cancers and in identifying those patients who will and will not benefit from a specific treatment, pathologists should be empowered to serve as principal investigators. One participant referenced the ORIEN research partnership, where pathologists have assumed a leadership role.

Hold molecular tumor boards. Pathologists can provide recommendations and rationales for testing, not only reading the report, but providing detailed recommendations. What are the molecular findings? What should we do in terms of molecular testing results.

Policy and Reimbursement

Biomarker testing is not the only area in oncology where policy and reimbursement trail behind advancements in the field; however, participants agreed on the urgent need for more clarity on coverage and for processes to accelerate policy updates to lessen confusion and uncertainty around payment. Despite the Centers for Medicare & Medicaid Services (CMS) finalizing a National Coverage Determination (NCD) for NGS testing in March 2018, summit participants posed a number of questions that reflected lack of certainty on how to interpret the NCD.

After a brief presentation, summit participant Katherine Szarama, PhD, Presidential Management Fellow, *Centers for Medicare & Medicaid Services (CMS)*, fielded questions from participants that included:

Whether CMS would cover repeat NGS testing? For example, can patients be tested to confirm if they are a clinical trial match? Which takes precedence: the NCD or the LCD?

Regarding one-time life NGS testing, a participant asked whether CMS had expert evidence that one-time testing is [effective]. "With lung cancer you need to test every time the cancer progresses. One-time life testing is not appropriate. It should be a lung cancer expert panel deciding, not just making it a general coverage decision," he commented.

Another participant added "monitoring patients over the course of time is going to become increasingly important. We need to be ready to reimburse for that." Ultimately this approach will save money over time "because it's doing the right thing for the patient, not just treating in the dark."

Dr. Szarama acknowledged that the transition period from when an NCD is finalized and when it is implemented is a "messy" time. Once the NCD is implemented it will supersede an LCD, she noted. Dr. Szarama reminded participants of the NCD reconsideration process through which requests can be made for a new NCD or reconsideration of an existing NCD. "It's reasonable to have discussion about what areas can be changed and improved over time," she said.

Participants also queried the role of third-party billing in implementation of the recent exception to Medicare's Laboratory Date of Service (DOS) Policy (also known as the 14-Day Rule). Oncology programs have identified CMS' DOS policy as a pain point in billing and reimbursement of molecular testing. On January 1, 2018, changes to the policy became effective with CMS added an exception to the existing laboratory DOS regulations that generally permits laboratories to bill Medicare directly for Advanced Diagnostic Laboratory Tests (ADLTs) and molecular pathology tests excluded from the Hospital Outpatient Prospective Payment System (OPPS) packaging policy. (See ACCC white paper on The Future of Precision Medicine and Clinical Diagnostics in Oncology for a detailed explanation of the policy's history and CMS' recent revision to its Laboratory DOS policy. Access the paper on the ACCC website at accc-cancer.org/pathology.)

Dr. Szarama told participants that CMS will be responding to questions about the role of third-party billing in implementation of the 14-Day Rule toward the end of 2018.

Following Dr. Szarama's remarks, participants joined in a discussion of policies around coverage and reimbursement for molecular testing with one participant calling attention to the multifactorial and complex nature of the problem. "If you have a broad payer mix, all payers have different policies" and at most institutions oncologists and pathologists have no idea what their program is being reimbursed for the testing. "We're dealing with 30, 40, or 50 percent of the payer mix being Medicare; many commercial payers follow Medicare guidelines, which they don't understand," commented another. As with all healthcare, the payer market is also experiencing rapid change, participants agreed. "We've found each payer isn't sticking to the historical tradition of following the Medicare NCD." Within a single payer, for example a Medicare Advantage plan, coverage variation can exist. "The challenge is how to democratize coverage and get consistency."

Yet another evolving issue is germline test. As incidental findings on molecular tests reveal the need for additional tests, "there's an opportunity in a stronger alliance between pathology and genetic testing," one participant commented. "We are starting to know if you have NGS testing, what's the expected rate of incidental results," she said. "At what point do we start changing in response to that?"

Challenges and Areas of Opportunity

Summit participants capped the discussion on policy and reimbursement by identifying the following areas of opportunity:

Track and aggregate policy and reimbursement "knowns and unknowns."

Educate. As an example, 60 percent of respondents in the ACCC survey reported that they were either not aware or unsure about how Medicare's new exception to the 14-Day Rule would impact molecular testing.[8] Opportunities exist to better educate providers and staff on policy, updates, and how testing coverage and reimbursement is affected.

Standardize internal policies within health systems, institutions, and practices. Despite lack of clarity in policy, opportunities exist for developing internal organizational policies that reflect choices about testing options and what will be accepted and what will not be accepted and why.

Determine "need to know." Participants saw an opportunity in determining or designating who needs to know and understand the nuances of policies for coverage and reimbursement so that the expectation is not that every individual professional is responsible for keeping up with payment policy. Instead, those responsible for tracking policy could inform internal institutional policies covering these areas.

Strengthen cross-discipline, cross-department communication. One participant noted the need within organizations for communication on coverage and reimbursement issues among departments and individuals who typically don't interact.

Develop patient-facing education. Participants agreed on the need to help patients understand the clinical treatment and financial implications, e.g., NGS patient education video. One participant explained: "The billing is so complicated. Patients get calls from the third-party lab. They didn't know that the test was $6,000. Then there's a bigger problem because patients are cancelling the tests."

Reaching Consensus and Next Steps

To bring the participants to consensus and develop actionable next steps, summit facilitator Robert Mittman asked participants to review the graphical recording boards on display around the meeting room. (See Appendix B for an example of the opening session graphical recording.) These recordings followed the summit agenda and captured key takeaways from the day's conversations on the state of cancer biomarker testing and molecular pathology, the diagnosis and treatment decision-making process, and policy and reimbursement issues. Participants were tasked with voting for opportunities they believed to be the most impactful (red sticker) and most feasible (blue sticker). Through this process, summit participants reached consensus on seven opportunities for improving the integration of pathology with the cancer care team. This was followed by one final working group session, during which participants outlined action plans for next steps.

Seven Areas for Opportunity

1. Empower Pathologists & the Oncology Care Team for Culture Change

Participants agreed that there is a need for a cultural change in both pathology and oncology. An opportunity to strengthen the pathologist's role in the cancer care team lies in empowering pathologists to become leaders and educators on the evolving importance of molecular pathology in cancer diagnosis and treatment. As the understanding and knowledge of the biology of cancer grows, pathologists have an opportunity to take an active leadership role in tumor board discussions, to educate on and lead biomarker test ordering, and to be recognized as integral members of the cancer

care team. Potential action steps toward this cultural shift include engagement of existing local resources, such as regional chapters of pathology societies; professional organizations like the Association for Molecular Pathology (AMP), College of American Pathologists (CAP), and American Society for Clinical Pathology (ASCP); and the identification and recruitment of local physician champions. Together, these organizations and leaders can offer clinical education on molecular pathology, guidelines, research and also provide training on non-clinical skills including leadership and communication. Leadership skills can be developed within model institutions and could become components of pathology residency programs.

2. Standardize the Testing Order Process

As the summit discussions revealed, testing is a complicated, multifactorial process, and it is increasingly required to provide quality, patient-centered cancer care.

Summit participants see opportunity in standardization of the testing ordering process for specific indications, thus enabling the cancer care team to provide high-quality cancer treatment across cancer types and tumor sites. With a standardized ordering process, oncologists, surgeons, those specialists performing biopsies, and pathologists will know what tests are necessary, how much tissue must be procured, and how much time it will take to deliver testing results and treatment options to patients. Such standardization can help cancer programs form a roadmap for testing, improve communication and decrease turnaround times. To monitor the process, a coordinated, centralized dashboard to track specimens and the testing process would be an asset. However, standardization regarding appropriate testing and reflex testing will require a nationwide effort based on evidence, participants concluded. To start, associations and societies can bring their resources together to identify and address gaps in standard operating procedures, lobby for testing coverage and reimbursement, develop sample reflex testing protocols, and categorize testing order protocols by disease state.

3. Improve Specimen Management

Ensuring the adequacy and quality of tissue as well as satisfactory service to patients depends on developing a consistent, seamless specimen procurement and management process, participants agreed. Optimally, the process would begin with a pre-biopsy consultation between the pathologist and the provider who will perform tissue collection. In the current landscape, pathologists are being asked to do more with less tissue; therefore, constant communication between pathology and other specialties is increasingly critical to inform the proper management of limited tissue samples.

Opportunities lie in identifying and adhering to best practices and guidelines for obtaining specimens, with surgeons and specialized physicians such as pulmonologists and interventional radiologists receiving mandatory training to facilitate guideline compliance. Adherence could be tied to compensation as a means of enforcement. Nurses at the bedside and technicians who work in the lab also need to be aware of proper tissue handling and storage requirements, participants agreed. Further resources that could be utilized to standardize and streamline specimen management include the implementation of prioritization matrices by tumor type, specimen algorithms, a real-time dashboard of metrics related to tissue quality and quantity (e.g., the National Pathology Quality Registry), and protocols such as those provided by the American Society of Clinical Oncology (ASCO), College of American Pathologists (CAP), and others.

4. Generate "One Pathology Report"

Summit participants strongly supported the potential of creating "one pathology report" for clinicians generated by standardizing data and language across specialties with the end-user in mind. Ideally, the "one pathology report" would be accessible across all specialties and all EHR systems; would allow for data mining to identify gaps; integrate artificial intelligence for interpretation; and be longitudinal, evolving over time. This would serve as a consistent way to collect and coordinate all relevant data, as well as determine levels of evidence and possible treatment options. Opportunities for developing a standard "one pathology report" start with leveraging professional societies' and oncology organizations' engagement in support of efficient, evidence-based, patient-centered care delivery. To begin, cross-specialty providers will need to define the elements of this report, which can vary across cancer type and tumor site, agree on the standardization of nomenclature, and identify indications of high quality. Next steps would include mapping out current sources and locations of information and identifying a point person to coordinate aggregation of required information. With the report structure determined and information sources identified, testing sites would be needed to standardize and establish the report as a best practice.

5. Optimize Virtual Tumor Boards

As pathologists' role on the cancer care team has not historically been patient-facing, they have less direct access to patients and patient records, often leaving them underprepared for tumor board participation. Neither provider nor patient is properly educated on the role and importance of molecular pathology in cancer diagnosis and treatment, and pathologists are not currently incentivized to provide this education.

Summit participants view greater utilization of virtual communication platforms (e.g., video-based webinars) as an opportunity to leverage technology to accommodate the busy pathologists' schedules, eliminate a travel/scheduling burden for pathologists in different locations from providers, and more effectively and efficiently incorporate pathologists' expertise. Virtual meeting platforms would offer a convenient way for pathologists to educate other providers and care team members, and even include patients and families when appropriate. To fully integrate pathology would require a multidisciplinary mindset so that all tumor board participants are actively engaged in the discussion. Participants noted that this would necessitate a means to incorporate lab data, claims data, biobank data, and patient records so that all participants have access to the same information needed to wholly address each patient. As first step in this process, participants suggested engaging electronic health record (EHR) vendors on the need for a platform that would enable migration of these data, and access to the information in formats optimized by a variety of end-users.

6. Strengthen the Alliance Between Pathology & Genetic Counseling

Summit participants noted that a stronger alliance between genetic counseling and pathology could lead to improved care coordination, stronger patient advocacy and support, and greater communication between clinicians and patients. To strengthen the relationship between these two departments, professional societies representing genetics, genomics, and pathology would need to coordinate efforts to establish mutual goals. Communicating the importance of this opportunity to departments on the front lines of care would be critical, participants agreed, as both pathology and

genetic counseling services are in high demand. Opportunities exist for pathology and genetics to collaborate on shared protocols, pathological interpretation, and division of labor, and in some cases to pursue joint pathology and genetic counseling projects.

7. Educate and Empower Patients

As cancer diagnosis and treatment decisions have become more complex, patients may find themselves in a position where they lack the perspective and knowledge to decide on their best course of action. Summit participants agreed that often patients do not adequately understand why tests are being ordered, how critical they are to proper diagnosis, what doctors learn from the results, and how they may impact treatment options.

To alleviate this issue, participant consensus was that patients should be empowered with the knowledge and resources needed to ask the right questions, collaborate with providers on treatment, and ultimately make the best medical and financial decisions for themselves and their loved ones—right test, right treatment, right time. Patient-facing resources including checklists, frequently asked questions (FAQs), and pamphlets from patient advocacy groups are currently available. Participants agreed that an opportunity exists to create additional resources on molecular testing, pathology reports, and how this information is used in cancer diagnosis and treatment. Clinical trial eligibility guidance, online learning modules, and caregiver/case management support are still needed. A patient-friendly version of the pathology report could be developed as an aid for clinicians in talking with patients about why the test was ordered, what the results show, and how the results impact treatment decision-making. To start, professional and patient advocacy associations should identify education gaps and opportunities for collaboration with the intention of providing patients with a central hub of educational resources. Best practices from model institutions can be identified by stakeholders and shared with patient groups.

Conclusion

A ground rule for all participants in the ACCC 2018 Integration of Pathology into Oncology Care Leadership Summit was engagement. The discussions, conversations, perspectives, and opinions expressed over the course of this one-day meeting reveal the energy, commitment, and passion participants brought to this challenge. As the knowledge and understanding of the biological and molecular forces behind cancers grows at an accelerating pace, the demand for biomarker and molecular testing is increasing in tandem. Cancer treatments are becoming more precise and patient identification, more nuanced. Now more than ever, pathologists play a pivotal role in the diagnosis and treatment of cancers, and delivery of quality care to the right patient, with the right treatment, at the right time.

ACCC would like to thank the summit participants for sharing their time and expertise to identify immediate opportunities for impactful action to bring oncology and pathology into closer integration, as well as to improve access to and appropriate utilization of molecular testing for the diagnosis and treatment of cancer.

Please visit the ACCC website at accc-cancer.org/pathology for updates.

References

1. 2018 ACCC Survey. *Understanding the Landscape of Pathology Integration with the Cancer Care Team.* Question 30.
2. 2018 ACCC Survey. *Understanding the Landscape of Pathology Integration with the Cancer Care Team.* Question 34.
3. 2018 ACCC Survey. *Understanding the Landscape of Pathology Integration with the Cancer Care Team.* Question 10.
4. 2018 ACCC Survey. *Understanding the Landscape of Pathology Integration with the Cancer Care Team.* Question 18.
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6. 2018 ACCC Survey. *Understanding the Landscape of Pathology Integration with the Cancer Care Team.* Question 7.
7. 2018 ACCC Survey. *Understanding the Landscape of Pathology Integration with the Cancer Care Team.* Question 34.
8. 2018 ACCC Survey. *Understanding the Landscape of Pathology Integration with the Cancer Care Team.* Question 24.

Appendix A – Summit Agenda

ASSOCIATION OF COMMUNITY CANCER CENTERS

INTEGRATION OF PATHOLOGY IN ONCOLOGY CARE: LEADERSHIP SUMMIT

Tuesday, July 31, 2018–8:30 AM - 4:30 PM
Hogan Lovells, Washington, D.C.

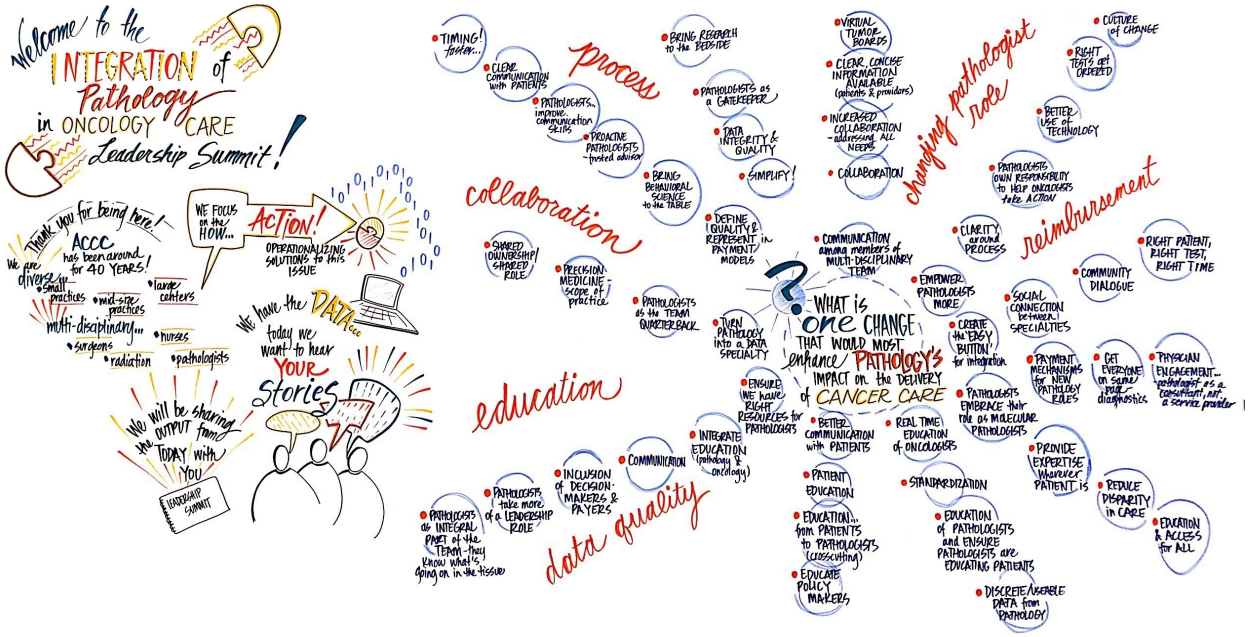
OUTCOMES

- Develop a list of opportunities to improve the integration of pathology into cancer care in community cancer centers in the following areas:
  - Cancer biomarker testing and molecular pathology
  - Cancer diagnosis and treatment discussions/decisions
  - Policy and reimbursement
- Develop plans for immediate actions in high-priority areas that could lead to improvement within the next year.

AGENDA

8:30 AM	**Registration and Breakfast**
9:30 AM	**Welcome and Opening Roundtable**
	Cancer Biomarker Testing and Molecular Pathology What is the landscape of cancer biomarker testing today? Given that landscape, what are opportunities to better integrate oncology and pathology in ordering and conducting biomarker and molecular pathology testing?
11:30 AM	**Networking Break**
11:45 AM	**Cancer Diagnosis and Treatment Discussions/Decisions** How are cancer diagnoses and treatment decisions made today? How involved are pathologists? What are opportunities to better integrate pathology and oncology in making treatment decisions?
12:45 PM	**Lunch**
1:30 PM	**Policy and Reimbursement** How do public policy and reimbursement affect the use of biomarker testing and molecular pathology in oncology? What are the opportunities to leverage policy and reimbursement for better integration?
	Prioritization of Opportunities Which of these opportunities would have the biggest impact on integrating pathology into oncology practice in community cancer centers? Which are the most feasible?
2:50 PM	**Networking Break**
3:10 PM	**Where Do We Go from Here? Action Planning** For the top-priority opportunities, what actions could this community take to move them forward?
	Wrap-Up and Next Steps
4:30 PM	**Adjourn**

Appendix B – Sample Graphical Recording



Association of Community Cancer Centers

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A publication from the ACCC education program, "Understanding the Landscape and Integration of Pathology with the Community Cancer Care Team." Learn more at accc-cancer.org/pathology.

The ***Association of Community Cancer Centers (ACCC)*** is the leading education and advocacy organization for the multidisciplinary cancer team. ACCC is a powerful network of 25,000 cancer care professionals from 2,100 hospitals and practices nationwide. ACCC is recognized as the premier provider of resources for the entire oncology care team. For more information visit accc-cancer.org or call 301.984.9496. Follow us on Facebook, Twitter, and LinkedIn, and read our blog, ACCCBuzz.

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