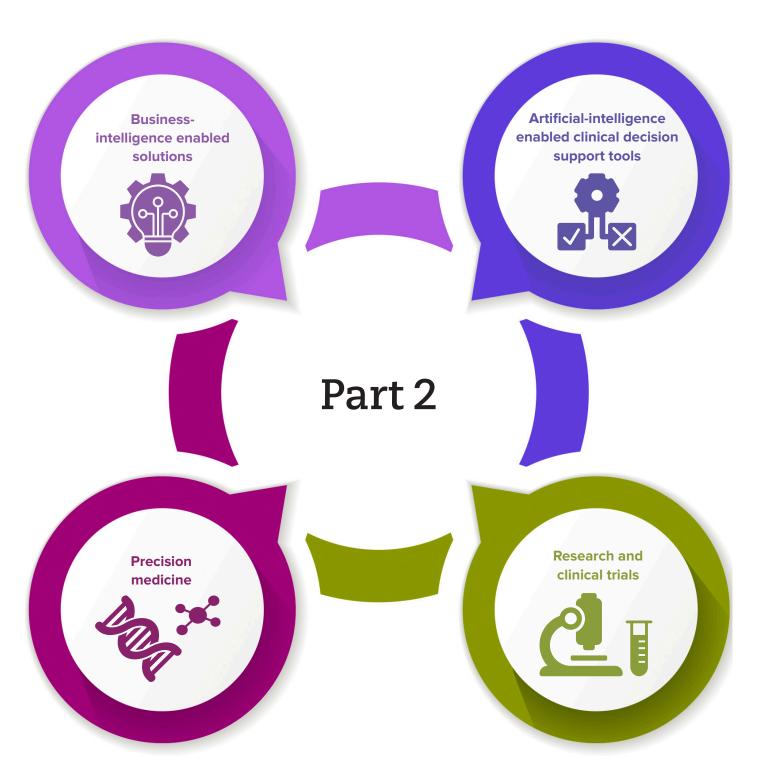
Trending Now in Cancer Care



n past years, the Association of Community Cancer Centers (ACCC) fielded an annual "Trending Now in Cancer Care Delivery" survey to its membership to gain insights into challenges they face and, most importantly, solutions to address those challenges. Unprecedented challenges from a global pandemic, a 3+ year public health emergency, and feedback that members did not have the time and/or resources to take this annual survey led ACCC to look for alternative ways to collect these data. In 2020, ACCC conducted a series of focus groups to produce the 2021 Trending Now in Cancer report. In 2023, ACCC hosted a series of interactive sessions at the ACCC 49th Annual Meeting and Cancer Center Business Summit (#AMCCBS) to collect insights and solutions into the 8 key areas. Below, we take a "deep dive" into 4 of these topics. Look for "Trending Now in Cancer Care Part I" in the Oncology Issues volume 38, number 4.1

BUSINESS INTELLIGENCE-ENABLED SOLUTIONS

Business intelligence (BI) tools and technology are helping today's cancer programs and practices to streamline clinic workflow and processes, improve business and financial operations, and mitigate workforce shortages by automating manual processes.

Facilitators

- Amy Ellis, Chief Operating Officer, Northwest Medical Specialties, PLLC
- Douglas Flora, MD, LSSBB; Executive Medical Director, Oncology Services, St Elizabeth Healthcare
- Jeff Hunnicutt, Chief Executive Officer, Highlands Oncology Group
- Ashley Joseph, Vice President, Client Services–Infusion, LeanTaaS
- Matthew Manning, MD, FASTRO; Chief, Department of Oncology, Cone Health Cancer Center

Challenges Facing Oncology

- How do we contain costs? Health care costs are on the rise, and oncology is one of the most expensive cost centers. These costs contribute to poor patient experiences, with an increasing number of patients with cancer having to file for bankruptcy due to treatment-related costs.
- How do we integrate technology into disease management?
- How do we access real-world data in real time and then apply it to practice?
- How do we ensure data privacy and security?
- How do we integrate new BI platforms with existing systems (eg, electronic health records [EHRs], electronic patient-reported outcomes [ePROs]) and processes (eg, triage, bundled payments).

 What are the ethical and regulatory concerns, and how do we address these concerns around big data and use of BI technology?

Information Overload

Today's busy providers are faced with so much data that they often do not know what to do with it. Some providers share that it may be asking too much for them to keep up with the barrage of data information coming at them. Yet most providers realize that we need to move away from intuition and that we must use these data for drug development, health equity, and improved cancer care delivery.

Defining Business Intelligence

BI is a term used to describe a set of techniques, processes, and technologies used to gather, analyze, and visualize data to make better, informed business decisions. BI can be used to:

- Streamline operations and processes, identify inefficiencies and redundancies, and then develop process-related improvements and efficiencies.
- Identify operational patterns and trends (eg, issues with scheduling and patient throughput and/or reimbursement challenges related to specific services or payers).
- Improve patient outcomes by providing clinicians with real-time access to patient data, allowing them to make data-driven decisions about care and treatment.

"Health care is late to the game compared to many other industries that are using and leveraging business intelligence and artificial intelligence technology to improve efficiency."

 Identify trends and pattens in patient populations. By analyzing large amounts of patient data (eg, demographic information, social drivers of health, treatment history, and outcomes), providers can gain a better understanding of patient populations they treat.

Rapid Uptake of BI Technology

Use of BI-technology is accelerating rapidly in the field of oncology, helping providers to manage their time and tasks and preventing problems before they occur. Yet many providers are not using this technology as efficiently as possible, and providers know that they can make better use of these technology platforms. Advantages to BI-enabled technology include:

- Automation of tasks that are time-consuming and repetitive, freeing up providers to spend more time doing direct patient care
- Increased efficiency in scheduling appointments
- Improved communication between healthcare providers
- Enhanced patient engagement
- Optimized resource utilization
- Streamlined diagnostic process
- Personalized treatment plans
- Reduction in treatment-related adverse events.

BI-Solutions in Practice

Real-Time Tracking Systems. To streamline its operations, St. Elizabeth Cancer Center in Edgewood, Kentucky, implemented a <u>real-time tracking system</u> of patients and equipment to identify both areas for improvement and inefficiencies. On arrival, patients receive a clipped badge that tracks their location so that providers can see in real time how patients are progressing through their center. This BI-enabled technology can be used to:

- Set a tolerance threshold for how much time patients should be allowed to wait, and to monitor patient alone time.
- Generate reports on the time from patient entry into the institution to examination by a provider, as well as capture patientprovider interactions.
- Identify bottlenecks, similar to the mechanism of an air traffic control system.
- Track behaviors or tasks in which providers are slow to improve processes or reallocate staff, if necessary.

Care Management. Northwest Medical Specialties, PLLC, in Washington State adopted the <u>Canopy Intelligent Care Platform</u> (Canopy Oncology) to help optimize staffing resources by reducing workflow redundancies and improving communications. This BI-enabled platform offers an easy-to-navigate ticketing (task) dashboard to help staff prioritize tasks and communicate with other team members about outstanding tasks and areas in which they may need support. For example, the analytics dashboard captures data that include the median time to pick up of tickets by staff and the median time for staff to close a ticket (address the issue or task). These data can be used to support decisions to reallocate tasks and/or staff as necessary. This BI-enabled technology platform allows these data to be integrated into the practice's EHR.

Infusion Center Optimization. Many infusion centers face challenges related to patient wait times and capacity management (eg, midday peaks, staffing and allocation of infusion nurses). Whereas some cancer programs have developed in-house solutions to improve infusion center operations, several BI-enabled platforms are available commercially. One such platform, iQueue for Infusion Centers (LeanTaaS), uses business and artificial intelligence (AI) technology to run thousands of simulations to identify scheduling templates that will work best for specific infusion centers. This type of predictive scheduling supports resources and staff allocation decisions. In her presentation, facilitator Ashley Joseph shared that the nearly 500 infusion centers that have adopted this technology report these data:

- 15% average increase in patients served
- 30% wait time reduction at peak times
- 25% average increase in provider satisfaction
- 50% average decrease in staff overtime.

Revenue Cycle Management. As staff at infusion centers seek technological solutions to optimize operations, those at cancer programs are developing home grown solutions and/or leveraging commercially developed BI platforms to perform revenue cycle tasks best suited to automation, freeing business and revenue staff to tackle issues that require human intelligence and intervention. BI technology can help cancer programs streamline revenue cycle management, achieve better understanding about payer policies and insurance claims data, and collect metrics on key performance indicators of cancer program business health.³

Data Collection, Analysis, and Reporting. Highlands Oncology Group in Arkansas is looking to normalize data in practice operations and analysis; this requires building algorithms to take individual data

reports and/or datasets and submitting them into 1 application to provide a single report with all data points brought together. This multisite practice is using the Microsoft BI platform to generate this report, with all data using the same terminology and then using these normalized datasets to review and analyze practice trends (eg, payments).

Use of Chatbots. Providers should look for opportunities to use this technology to execute repetitive and time-consuming administrative tasks, like writing recommendation letters for staff and supporting charting efforts.

Radiation-Oncology Specific Considerations

Automation. The potential exists for technology to inform and execute treatment plans with minimum human intervention and its attendant errors. Radiation oncology is a field with many processes and tasks that could benefit from automation; these include treatment planning, contouring, image registration, treatment field transfer from the treatment planning system to the treatment delivery system, radiation delivery recording and verification, data aggregation for analysis of radiation treatment, and quality assurance checks.

Revenue and Financial Implications. Cone Health of North Carolina used a BI platform to develop a digital preauthorization checklist for radiation oncology and financial navigation staff to track prior authorizations. The health system also uses BI-enabled technology to analyze reimbursement data and look for billing errors, allowing staff to adjust as needed.

Performance. BI-enabled technology supported the build of an in-house performance dashboard that Cone Health uses to track trends across the Radiation Oncology Department and to collect and analyze performance metrics data. For example, staff members collect metrics on linear accelerator on time status and time to treatment and analyze data to see which tasks are taking more time and where efficiencies can be realized.

Small Group Discussion

After the series of facilitated presentations and discussions, meeting participants split up for small group discussions. Below are the reports from these discussions.

Group 1. Discussion revolved around using BI technology to drive efficiency.

"There's room for efficiency improvement across all settings—community and academic. Keeping the end user experience in mind is the common theme we discussed. What does the end user experience look like? And how can we make change easy for clinicians, as well? Take a location tracking system, how much is that [technology solution] taking providers out of the clinical workflow to implement? [We also talked about] the importance of ePROs going forward and what that's going to look like as time goes on. How do we action these insights? How do we analyze these datasets and create the right efficiencies?"

"Oncology providers are open and interested in embracing technology, as often these providers are inundated with so many administrative tasks they feel that they are already 2 hours behind at 6 am."

Group 2. Discussion revolved around using BI technology to improve the patient and provider experience.

"Our group talked about Midmark's real-time location system and its impact on patient experience, because we're decreasing wait times. We talked about its impact on staff satisfaction, because now our nurses and team members essentially know where our patients are at all times. We talked about how this BI technology solution could work in tandem with a solution like iQueue, because we're maximizing providers' schedules. And if providers are taking longer to see patients, these technologies allow us to modify patient and provider schedules to be more efficient. The downstream impacts are improved staff, clinician, and patient satisfaction."

"That discussion led into a conversation about physician burnout, which we are seeing across the board, and the importance of quality of life when managing physicians. [We talked about] the importance of culture and how the right culture can help manage physician burnout and attract physicians to your organization—all very helpful in a competitive market."

"Then our discussion turned into a conversation about the importance of patient navigation...how new solutions like Jasper (Jasper Health) [a digital guiding and navigation experience that improves the lives of individuals affected by cancer and their caregivers] take many patient navigation components and turn them into a technology solution, allowing patients to watch video programs and such, to help support our patient navigators and improve the patient experience."

Group 3. Discussion revolved around barriers to using technology, the relationship between technology and people, its impact on revenue, and more.

"There are definitely barriers to implementing [bi-enabled technology] in terms of cost versus return on investment. How do you decide what technology solution(s) to adopt? How do you decide when to invest in a technology solution versus hiring another FTE [full-time equivalent]? [The group believed] that technology does provide some sustainability in terms of workforce shortages and reducing burden on existing staff. Potentially, technology can help do more work with fewer team members. We talked about automation in general and got into the automation driver discussion and ethics: what happens to your labor force as you begin to replace their responsibilities?"

"[Our group] talked about how BI and AI must train on existing historic data, which may not predict the future. How does infusion software account for how things are changing? For example, what happens when a medicine that was once an 8-hour infusion is now just an injection?"

"We talked about how BI allows the analysis of broad swaths of information. On any given day, you can see how busy the infusion clinic is, whether the staffing level is appropriate, and patient wait times. [With BI technology], some inefficiencies pop up, like patients sitting in infusions chairs while waiting for preauthorizations. We view these tech solutions as tools or helpers, but not problem solvers. You still need humans to implement solutions and solve problems."

"We also discussed the revenue cycle. Using BI [technology], you can look at your patient population in terms of, 'What's our payer mix of Medicare, private, self-pay?' [You can] then use predictive analysis to see how your revenue is going to look based on who's in

your clinic that day. You can also use BI to analyze your data by clinic or by provider, allowing you to drill down on outliers and discover issues like high overtime utilization."

"Finally, we talked about the 99% of the time patients are not in your clinic. One percent of their life, they're sitting right in front of you; the other 99% they're not. BI-enabled registries can track when patients miss appointments and notify providers to keep patients from falling through the cracks. The technology then becomes a health equity tool. ePROs [are], too, as the technology facilitates check-ins with patients when they're not physically in the clinic."

Group 4. Discussion revolved around data, how to acquire data, and what to do with the data once you have it.

"In health care, in general, we tend to see screenings taking place in departments. And then departments try to figure out where that data and information go. What we need to do is develop a model where the screening is completed by the same individuals, at established times, and who are then responsible for filtering these data to the appropriate departments."

Group 5. Discussion revolved around post-COVID-19 trends like urgent and 24/7 care.

"We talked about trends [that] we're seeing post-COVID, which took us to the topic of urgent care and using BI-enabled technology to try to get ahead of things so that there's better predictability of who's going to come into [the] clinic. We spent time talking about cancer being a 24/7 medical condition, with infusion centers, most clinics, and many supportive care services offered only Monday through Friday."

ARTIFICIAL INTELLIGENCE-ENABLED CLINICAL DECISION SUPPORT TOOLS

Artificial intelligence tools and technology are helping today's providers work faster and smarter with consensus-driven clinical pathways and processes to measure and report adherence to evidence-based guidelines and algorithms that help proactively identify at-risk patients and guide follow up and early interventions.

Facilitators

- Olalekan Ajayi, PharmD, MBA; Chief Operating Officer, Highlands Oncology Group
- Douglas Flora, MD, LSSBB; Executive Medical Director, Oncology Services, St Elizabeth Healthcare
- James Hamrick, MD, MPH; Vice President, Clinical Oncology, Flatiron Health
- Rebecca Maniago, PharmD, BCOP; Associate Director, Clinical Oncology, Flatiron Health
- Matthew Manning, MD, FASTRO; Chief, Department of Oncology, Cone Health Cancer Center

Defining Al

AI is the development of computer systems that can perform tasks that typically require human intelligence; these include recognizing patterns, making decisions, and solving problems.⁴ AI has the potential to revolutionize the health care industry by enabling us to diagnose diseases and develop personalized treatments faster and more accurately than ever before. Today, AI platforms are helping providers quickly and accurately diagnose cancers and develop customized treatment plans based on the unique characteristics of each patient's disease. The technology has the potential to significantly improve patient outcomes and increase the speed and accuracy of diagnosis. AI platforms also are being used to analyze vast amounts of medical data and identify new treatment strategies based on the analysis of large clinical datasets. The technology has the potential to significantly advance our understanding of cancer and accelerate the development of new and effective treatments. AI is also expected to help cancer programs and practice:5

- Generate revenue
- Be more competitive
- Improve workflows and processes
- Recruit talent.

"Artificial intelligence has infiltrated our lives whether we're aware of it or not.

And if you're not aware of this technology, you are already behind."

Robotic Process Automation and Our Workforce

Cancer care and cancer treatment are complex; today's providers must digest enormous amounts of information to deliver care that is tailored to the individual (ie, precision medicine). Combined with increases in administrative burdens related to patient documentation, data collection, prior authorization requests, and more, these factors are all contributing to rising levels of burnout among clinical and non-clinical providers. In turn, this burnout is exacerbating health care workforce shortages across disciplines and specialties. So, how can AI help? Providers can train AI to take over and complete tasks; **robotic process automation** is a term for technology that automates

manual, repetitive tasks through the use of software robots. Not only will robotic process automation alleviate burnout and help ensure providers are working at the top of their license, but it can increase the accuracy of tasks, reduce costs, and streamline processes. Successfully robotic process automation follows these 4 steps:

- 1. **Define the process** (identifying the process that can be automated and the desired outcome).
- 2. **Design the automation** (creating a plan for how the automation will be implemented).
- Test the automation (running tests to ensure the automation is working correctly).
- 4. **Deploy the automation** (putting the automation into production and monitoring its performance).

Today's oncology programs and practices are using robotic process automation to do patient registration, complete prior authorizations, streamline workflows, code and bill for services, and accomplish claims adjudication.

Al and Health Equity

Half of physicians (51%) believe that they have little to no time/ability to effectively address their patients' social drivers of health. Most physicians want greater time and ability to address these (87%) but believe that addressing social drivers of health contribute to burnout (83%). And that's where AI can help. Prescriptive analytics platforms can collect large amounts of data on social drivers of health and combine AI algorithms with machine learning techniques to identify at-risk patients (ie, those with a higher chance of experiencing poor outcomes).

So how does this technology work? First, patients are identified as part of a population of interest (eg, Black women with metastatic breast cancer). Prescriptive intelligence then collects and/or purchases historical, nonclinical data and imports patients' current clinical data into the provider's EHR.⁸

Jvion offers a commercially available prescriptive analytics platform

"Artificial intelligence is only as good as the models we use to train this technology; that makes our data so important!" "The oncology program of the future may have an AI assistant for every practicing physician to support operations and allow physicians to spend more with patients."

that generates patient-specific, dynamic, and actionable insights that help inform appropriate resource usage and initiation of downstream workflows. At Northwest Medical Specialties, PLLC, a patient care coordinator team tracked these insights, reviewed flagged patients, EHRs, and risk factors, and recommended interventions for mediumto high-risk patients.⁷

Another commercially available platform is AdaptX, a cloud-based platform that collects patient data that providers can monitor, evaluate, and use to improve the quality, equity, and efficiency of patient care. At Modern Healthcare's virtual Social Determinants of Health Symposium—held on August 11, 2022—Daniel Low, MD, chief medical officer at AdaptX, explained that this technology adds an equity layer to health care by using AI to scan an organization's EHR for racial, language, and gender disparities either throughout the care continuum or among patient outcomes. Crunching vast amounts of data, this system accomplishes in a few minutes a feat that would take a team of analysts years to do.

In 2021, the National Cancer Institute's (NCI) Small Business Innovation Research Program solicited proposals for the development of oncology-specific software to address <u>social determinants of health in oncology practices</u>. ¹⁰ Last year, ACCC reported on works in progress from 3 recipients of this NCI funding: ¹¹

- Pistevo Decision. This integrated, multilevel, decision support platform will include a patient-facing application (app) to empower patients to answer social determinants of health screening questions when it is comfortable and convenient for them. In developing the platform, the company is engaging with stakeholders from the oncology community (eg, Johns Hopkins Medicine oncologists, patient advocates, community-based social services, staff at Johns Hopkins Bloomberg School of Public Health).
- <u>Pieces Technology</u>. This company is partnering with NCI Community Oncology Research Program members to develop a workflow and tools to identify patients with social determinants

- of health needs. The company's platform, Pieces Connect, brings together patient assessment and integration of positive screening data, closed-loop referrals, and access to pertinent community-based organizations.
- XanthosHealth. The ConnectedNest platform is an EHRenabled mobile health technology developed in partnership with researchers from the University of Minnesota to safely and securely collect data on patients' social risk factors (eg, housing, transportation, financial, social support).

Al and Clinical Decision Support Solutions

Clinical decision support solutions augment complex decision-making for clinicians. There are 2 basic types: knowledge-based and non-knowledge-based. Knowledge-based clinical decision support tools use AI to develop rules (also called *if-then statements*), retrieve data, and produce an action or output. Non-knowledge-based clinical decision support tools use AI, machine learning, and/or statistical pattern recognition to better inform clinical treatment decisions. AI-enabled clinical decision support tools help providers in many areas:

- Patient safety is supported with tasks like automated quality
 assurance in radiation oncology, gravimetric verification of dose
 using robotic pharmacy technology, and identification and
 elimination of drug-drug interactions. (Note: Use of AI in this
 area can result in providers experiencing alert fatigue.)
- Clinical management is supported with tasks like adherence to clinical guidelines that improve quality and standardize care, follow-up and treatment reminders, and chatbot follow-up visits. (Note: Use of AI in this area can result in a negative impact on user skill as users come to trust and rely on

"Clinical decision support tools are really point-of-care support, helping to get the right information to the right person at the right time."

- the system.)
- **Cost containment** is supported with help in reducing test and order duplication and suggesting more cost-effective medications and/or treatment options (eg, a biosimilar strategy).
- Administrative functions are supported with tasks like diagnostic code selection, automated documentation, and note auto-fill capabilities.
- Diagnostics support is supported by provision of suggested diagnosis based on patient data and imaging, laboratory results, and pathology reports.
- Patient decision support is assisted by analysis of and reporting on data from individual health records. (Note: This support may require technological proficiency on the part of the patient.)
- *Improved documentation* is supported with aggregation of large amounts of data across multiple sources. (Note: Use of AI can lead to note bloat and/or propagation of erroneous data.)
- Workflow improvements.

Cancer programs can develop and implement their own clinical decision support solutions (homegrown solutions) or adopt one of many commercially available clinical decision support solutions. For example, <u>Flatiron Assist</u> is an oncology-specific, evidence-based clinical decision support tool. This customizable tool is embedded in the EHR and provides:

- Decision support, entailing standardized clinical pathways, real-time updates incorporating National Comprehensive Cancer Network (NCCN) Guidelines and other recent evidence, and the ability to track regimen usage.
- Research support, involving the ability to match clinical trials based on specific patient factors and to collect data on eligibility criteria, study protocol, and research team contact information.
- Administrative support, entailing data collection for prescribing patterns and maintenance of key prior authorization data within the EHR.
- Opportunities to collaborate with payers.

Small Group Discussion

After the series of facilitated presentations and discussions, meeting participants split up for small group discussions. Below are the reports from these discussions.

Group 1. Discussion revolved around EHRs and how AI can improve data collection, reporting, and sharing.

"Overall, EHRs are finally achieving their goals in being usable and adding value. But the biggest challenge is interoperability, and a main barrier here is lack of standards when it comes to terminology and data, especially when it comes to genomic data. Our group talked about how, as genomics become more and more important, AI could be a helpful tool in interpreting and standardizing that data for better data sharing. AI is a promising investment to support the patient experience when they're not in the 4 walls of your clinic—in other words, using AI to help manage care and track patients in the home setting. This

technology is helping to improve treatment adherence and the overall patient care experience."

"We also talked about how AI requires money on hand. And so many cancer programs and practices are struggling financially after a 3+year global pandemic. Many are only now getting back up to speed when it comes to funding innovations."

"In oncology, we see AI less of a game changer and more of a game accelerator, because we have to be careful and methodical in this space. One area that we see AI as having a really big impact is overhauling the revenue cycle and reducing the staff required to maintain billing operations. A big place for improvement is in prior authorizations, where our group thought AI can help providers eliminate delays and challenges."

Group 2. Discussion revolved around using AI to improve revenue cycle management.

"Our group also talked about using AI and bots to look at revenue cycle processes. At my cancer program, our patient population is very heavily managed-care patients; [only] 20% [of our patients have] traditional Medicare. Most of our patients require prior authorization, so that is one of the key areas that we are looking at. Our EHR is lacking in a lot of the functionality that we need, so we constantly struggle with adding applications to help. Many applications do not currently have interfaces that work with our EHR."

"We had a lot of conversations around interactions with pharma and how that has changed. How pharma has helped providers over time. We've seen that change since managed-care plans now have preferred drugs that they want providers to utilize."

"We had discussion around patient portals and the utilization of those platforms—for example, whether the platform is inside or outside of the EHR, and what the patient experience looks like. We see automation and AI as the next big investments for oncology." "AI will not replace health care providers. Instead, this technology can support providers and help bring back the humanity in medicine."

Group 3. Discussion revolved around current use of Al technology at participant's cancer programs and the need for continued investment and evaluation of its impact on patient care.

- Midmark's real-time location system
- AI-supported mammogram screening
- AI-supported digital pathology
- AI-supported analysis of urine specimens
- AI-supported prior authorization workflows aimed at reducing the number of denials
- AI-supported scheduling in the infusion center
- Curation of regimen libraries like <u>OncoEMR</u> (Flatiron), which has over 3000 regimens spanning more than 90 diseases

RESEARCH AND CLINICAL TRIALS

Across many fronts, the oncology community is working to make research more equitable, enrolling diverse patient populations into clinical trials, making this type of care standard in all communities, and spurring adoption of new models (eg, decentralized and virtual clinical trials).

Facilitators

- Christa M. Braun-Inglis, DNP, APRN, FNP-BC, AOCNP; Nurse Practitioner/Assistant Researcher/CCDR Lead, University of Hawaii Cancer Center
- Jennie Crews, MD, MMM, FACP, FACCC; Associate Chief Medical Officer, Ambulatory Care, Stanford Health Care; and Chief Medical Officer, University HealthCare Associates, Stanford Cancer Center
- Randall A. Oyer, MD; Medical Director, Penn Medicine Lancaster General Health, Ann B. Barshinger Cancer Institute

The Importance of Clinical Trial Participation in Cancer Research

Data from a seminal 2016 study by Unger et al strongly suggested that a "clinical trial system that enrolls patients at a higher rate produces treatment advances at a faster rate and corresponding improvements in cancer population outcomes." The authors wrote, "Viewed in this light, the issue of clinical trial enrollment is foundational, lying at the heart of the cancer clinical trial endeavor." Even with this knowledge, the data show that clinical trial accrual remains a challenge for cancer programs and practices: 13

- Overall, approximately 6% of adults with cancer enroll in treatment trials; enrollment in nontreatment trials is higher (biorepository, 13.4%; registry, 8.1%; prevention, 6.4%).
- Accrual rates at National Cancer Institute- (NCI-) Designated Cancer Centers average 18.9%.
- When asked, 70% of Americans expressed interest in clinical trial participation, and more than 50% of patients said that they would participate in a clinical trial if offered the opportunity.
- Investigators in 24% of cancer clinical trials fail to accrue over 50% of goal.

Bottom line: lack of clinical trial availability in the community and lower participation in clinical trials is slowing our progress in alleviating the burden of cancer.

"The community belongs in oncology research, and oncology research belongs in the community."

Increasing Racial and Ethnic Diversity in Cancer Clinical Trials

In 2020, ACCC and the American Society of Clinical Oncology (ASCO) entered into a partnership (the ASCO-ACCC Joint Initiative) to increase racial and ethnic diversity in US cancer clinical trials, with a specific focus on Black and Latino/Latina patients. The 2 organizations convened an expert, blue-ribbon panel, which included representatives from the FDA, the NCI, academic institutions, community cancer programs, and, most importantly, patients and patient advocates. Within 2 years, the 2 organizations published the ASCO-ACCC research statement, "Increasing Racial and Ethnic Diversity in Cancer Clinical Trials: An American Society of Clinical Oncology and Association of Community Cancer Centers Joint Research Statement," which outlined 6 recommendations to increase diversity in research participation:¹⁵

- 1. *Improve access*—every person with cancer should have the opportunity to participate in clinical trials, as an integral component of high-quality cancer care.
- Equity-focused design—trials should be designed with a focus
 on reducing barriers and enhancing equity, diversity, and
 inclusion (EDI) and work with sites to conduct clinical trials in
 ways that increase participation of underrepresented
 populations.
- 3. **Partnerships**—clinical trial sponsors, researchers, and sites should form long-standing partnerships with patients, patient advocacy groups, and community leaders and groups.

Health System	Organizational	Payer	Provider	Patient
Barriers	Barriers	Barriers	Barriers	Barriers
eg, escalating costs	eg, overly- burdensome institutional review boards	eg, prohibitive reimbursement policies	eg, physicians reluctant to enroll patients due to logistical and practical concerns	eg, practical concerns like lack of transportation or childcare services

- 4. **Education and training**—those designing or conducting trials should complete recurring education, training, and evaluation to demonstrate and maintain cross cultural competencies, mitigation of bias, effective communication, and a commitment to achieving equity, diversity, and inclusion in clinical trials.
- Invest in equity, diversity, and inclusion—research stakeholders should invest in programs and policies that increase equity, diversity, and inclusion in clinical trials and in the research workforce.
- 6. Sharing data and strategies—research stakeholders should collect and publish aggregate data on racial and ethnic diversity of trial participants when reporting the results of trials, programs, and interventions used to increase equity, diversity, and inclusion.

The ASCO-ACCC Joint Initiative released resources to help research sites increase the racial and ethnic equity, diversity, and inclusion in cancer clinical trials. The Just ASKTM Training Program and Site Self-Assessment are available free of charge and represent a full and complementary set of resources that can help research sites address barriers to participation in cancer clinical trials among racial and ethnic populations that have been historically underrepresented.

- The ASCO-ACCC Equity, Diversity, and Inclusion Research
 Site <u>Self-Assessment</u> helps research sites identify systemic areas
 that are known to affect the diversity of clinical trials and
 provides site-specific recommendations to modify rules and
 procedures.
- The Just ASK™ Training Program identifies opportunities for change at the individual level and provides real-world examples to enhance understanding of participants.
- The Just ASKTM Training Facilitation Guide helps providers continue the conversation around implicit biases after the initial training.

Cancer Research Workforce

In addition to the physicians and advanced practice providers (APPs) who act as principal and subinvestigators, research teams include administrators, coordinators (research nurses, research associates), regulatory experts, data managers, community health educators, and patient advocates. These teams face great challenges, including the *great resignation* of the health care workforce that partially was a response to the more than 3 years of the COVID-19 pandemic and

an aging health care workforce. ¹⁶ While some cancer programs have successfully brought retired, experienced research professionals back to work, this solution is short-term. The oncology community needs to identify long-term solutions and that means bringing younger people into the field of clinical research. Many research coordinators are not planning on that position as a career; they may have a bachelor's degree, and they eventually may enter other professional schools, like medical school. The oncology community needs to figure out how to better sustain the cancer research workforce, and that means building out career ladders and opportunities for advancement for all members of the research team.

Meanwhile, to improve clinical trial accrual, the cancer research workforce needs to take certain steps:

- Work together to improve the conduct of clinical trials. Leaders need to lead, be inclusive, and recognize everyone's value in the process.
- Recognize that principal investigators do not always have to be physicians. Principal investigators can be APPs, including pharmacists, depending on the clinical trial.
- Ensure that clinical research is accessible, affordable, and equitable for patients and sites.
- Help to design more pragmatic and efficient clinical trials that are better integrated into routine clinical care.

"Administrators are so key to research. If your cancer program administration is not involved in research or doesn't believe in it, then your research program is simply not going to work."

- Work with industry and trial sponsors to simplify, streamline, and standardize protocol requirements and research operations.
- Recruit, retain, and support a well-trained clinical research workforce. These efforts may include salary reviews and salary increases.
- Promote appropriate oversight and review of clinical research conduct and results.
- Work with the state's licensing body to ensure APPs can
 participate in clinical trial research. Coordinating with legal,
 regulatory, and IRB bodies paves the way for APPs to act
 as principal investigators.

"I want to underscore
the importance of community
health educators in
helping to inform and educate
the community about
clinical trials."

The Role of APPs in Clinical Trials

There is a movement to increase use of APPs in clinical research—not only as principal investigators of clinical trial conduct but also as leaders of other types of trials outside of treatment trials (eg, supportive care trials, cancer care delivery trials, and registry trials). Many times, APPs are the providers who spend the most time with patients; they know the specific needs of each patient and are experts in identifying those most suited to participate in clinical trials. ¹⁷ The time required to introduce and educate patients about a clinical trial is a recognized barrier to accrual. With their deep understanding of cancer, cancer treatment, and symptom management, APPs are uniquely trained and positioned to facilitate these discussions with patients. ¹⁸ As noted by Ulrich et al, APP "knowledge and expertise can lead to a more thorough discussion augmenting specific trial information provided by other members of the research team."19 To achieve a model in which APPs are active in conducting trials, it is very important to have a physician champion.¹⁷

During open discussion, 1 participant shared that her cancer program found APPs working in the clinic—and not in the research department—to be a barrier to increasing use of APPs in clinical research. Conference participants shared several solutions to this challenge, including:

 Creating a culture shift that promotes clinical research as a component of the care provided in clinic, better integration "The data
start with the
investigator. If investigators
don't provide good clinical
trial conduct and document
appropriately, then it's a real
headache for our research
coordinators and
data managers."

between research and clinic teams, and specific and targeted training and education on clinical research for APPs in the clinic.

- Hiring a clinical research APP with the expectation that this APP would be the provider for patients on clinical trials. The APP would build a portfolio of clinical trials, becoming the provider who best understands these trials and ways to best screen for these trials in the clinic.
- Partnering APPs who work in the clinic and who are already
 well-trained in the diseases, symptoms, and assessments with
 physicians to provide training that would allow APPs to assume
 care of patients enrolled to a specific clinical trial.

We've had research coordinators bring a feasibility study into a meeting and share feedback of issues they have identified. If physicians don't listen to this feedback and push the study through, it is the research staff who is then tasked with working out these issues. To avoid situations like this, we need to value everyone's input."

The Role of the Oncology Nurse Navigator

To increase clinical trial accrual, Virginia Cancer Specialists, PC (a large, multidisciplinary, community-based oncology practice in Northern Virginia) created the role of a clinical trials navigator to fill knowledge gaps of the practice's trial portfolio, provide introductory education on clinical trials to patients, and coordinate patient-related logistics. ²⁰ Today, the clinical trials navigator is the primary source of research information across the practice, including all satellite sites. Clinical trials navigator responsibilities include: ²⁰

- Crafting specific and dynamic recruitment plans and identifying gaps in processes or training
- Making routine visits to all clinic locations for personalized assistance
- Assisting providers when they have questions about patient eligibility prior to consent
- Performing phone triage for referring providers and patients who are interested in a clinical trial
- Identifying, developing, and maintaining relationships with key contacts at each of the practice's locations to facilitate timely fulfillment of accrual targets
- · Attending research meetings
- Working with patients to answer their questions about clinical trial participation.

Two years after implementation of this new role, the clinicals trials navigator receives referrals from providers practice-wide and identifies all clinical trial opportunities appropriate for patients. More, the practice continues to grow a portfolio of varied clinical trials, attracting external patients from across the region and the country.

Industry's Role in Clinical Research

During open discussion, an industry participant asked, "From the provider perspective, how would you define a good trial sponsor? In other words, do you have specific advice for helping industry become better partners on clinical trials?"

A provider offered 3 recommendations:

- 1. First, industry should look at underserved communities and figure out how to bring trials to the people who live in those communities. Industry should "make it their mission to look at a map of the United States and say, 'There are no clinical trials for people who live in this part of the United States.' Find out who those people are, and bring the clinical trials to them. And you will be rewarded with unique perspectives."
- 2. Second, industry should invite more people to the table when designing clinical trials to gain insight into patients' and providers' barriers to participation. What support(s) do patients need? Are there patient and provider concerns? What patient and provider education is needed? "It doesn't work all that well to design the whole package and then say, 'Now, let us tell you about this clinical trial and see if you can do it.' You will have a much better product when you have providers involved from the beginning."
- 3. Lastly, industry should report back to communities about the benefit of their clinical trial participation. "It builds a learning community. It builds a trust community. It spreads the word. It's helpful to go back to people and just say, 'Thank you.'"

"We see the problems facing our population health counterparts at community health centers. They build navigator teams, but they keep losing team members because of a lack of career pathways for these professionals. And when these individuals go out the door, they take with them all the knowledge they have acquired about the patients in their community. So, how do we keep our research coordinators and research navigators engaged in the work, engaged in the clinical research process?"

"That is true for clinical research coordinators and data coordinators as well. Unless you have a robust research program where there is a tiered staffing structure or a way for these professionals to move into a career ladder, retention is difficult. It was mentioned earlier that many people use research coordination as a steppingstone to something else, but not everybody [does]. And for those that don't, there really isn't a great career trajectory."

Another provider participant suggested that when industry takes a clinical trial to an academic institution (many of which have community networks), the sponsor shares its expectation that the academic institution extend the clinical trial to its community network. "I hear from colleagues in my network that these clinical trials are too specific or too complicated or that patients need to come to an academic center to participate. I don't think that's true. And we need partners who are advocating for those community cancer programs that are capable of participating. [For industry] to put that kind of pressure on when you are engaging with academic institutions for your studies will really help." Pharma has to be a bridge and help community research programs build the infrastruc-

ture required to participate in clinical trials and fund those infrastructure improvements.

One provider participant asked industry to think about the patient populations that each clinical trial serves and then design that trial for cohorts mapped to that population. Not only would that improve equity, diversity, and inclusion in cancer research, it also requires industry to go into the community to accrue patients who are not coming to the academic medical center.

Several providers brought up the costs related to clinical trial participation. Industry funding needs to support the total cost of the clinical trial. If participation in a clinical trial is likely to have negative financial impact on the cancer program's bottom line, organizations are likely to say, "No," to participation.

"I would ask that industry
think about this: we have all these
drugs that are [FDA] approved, but my
Pacific Islander patient population reacts
very differently to these drugs and their
toxicities—and that's the same with older
adults. So, consider sponsoring some of
your phase 4 trials with these patient
populations in mind; you would then
be able to collect better data for
drugs already approved."

Small Group Discussion

After the series of facilitated presentations and discussions, meeting participants split up for small group discussions. Below are the reports from these discussions.

Group 1. Discussion revolved around funding and clinical trial budgets.

"When negotiating clinical trial budgets, there is usually a line item for coordinator time and effort—in addition to PI [principal investigator] time and effort, we should negotiate more money for clinical trials with higher acuity (for example, lymphoma and leukemia patients who require more time and effort). More care coordination and management. So negotiating with industry and other entities so the budget reflects the cohort of patients being managed, (their acuity level), and the provider work required. This additional money

"Depending on the clinical trial, the amount of funding we receive from the sponsors for the trial work is significant. Some of these unique patient populations require a [provider] workload that is not easily recognized—whether it's the care coordination or the level of community resources needed [for patients to participate]. So, I would say appropriate funding of clinical trials is an imperative for sponsors."

might allow cancer programs to fund an additional FTE [full-time equivalent] to support existing research staff."

"We've been asked to help find more money for physicians [to participate in clinical research]. We first ask, 'How are you using your research staff to support your physicians? Have you developed patient education on research and clinical trials to save physician time on patient education?'"

"We talked about budgeting for a clinical trials navigator. And maybe it's not just for 1 trial. Maybe you are accruing to 5 different industry trials, and each 1 has a percentage of an FTE budgeted for a clinical trials navigator."

"Our patient population is underserved, so I know that for many of these patients, clinical trial participation will require resources for transportation and childcare. And I put those costs into my research

"More and more of my clinical trials include a thank-you card and how to get more information from the trial sponsor when the trial is complete. I've seen a big switch in how industry is approaching their provider relationships, and I've appreciated that change."

budget. IRBs allow that kind of support now. It is not enticement; it is taking care of the patient's financial reality, thereby improving patient access to clinical trials."

Group 2. Discussion revolved around institutional support and physician champions.

"There's only so much that pharma can do [around reimbursement]. [Successful research programs] have the right institutional structure. If you are going to adopt the hub-and-spoke research model, it needs to be leadership supported throughout the health care system and each institution.

"One thing we've found when we work with our hospital and physician groups to increase their clinical trial enrollment is physicians who say, 'It takes too much time for us to do that.' The real gamechanger is a physician champion who can get the rest of the physicians to come along."

Group 3. Discussion revolved around implicit bias and improving health equity.

"Our group identified 1 concrete action we could start with, and that was exploring implicit bias training for PIs and research staff—working to overcome our own biases on who is a clinical trial patient. Starting with ourselves and then spoke-wheeling implicit bias education and training out to our colleagues."

"How many practices or programs actually understand the patient population they currently serve? How many know the racial and ethnic makeup of the patients they are enrolling to clinical trials? I am going to be honest. My program didn't know how to do that [collect that type of patient information] until we took the research site assessment tool. So, we've only been collecting these data for between 9 to 12 months. But you don't know if you are actually improving diversity in clinical trials until you measure your efforts. We are novices at this type of exercise."

"Some research programs have navigators for specific disease sites or for specific ethnic or racial groups. That's an opportunity and a responsibility for our institutions—to bring in these types of community navigators to provide training and deployment. It not only enriches our workforce; it enriches the individual, their family, and the community they live in. These navigators take the health information, what they've learned about cancer, and the opportunity to participate in clinical trials back to the community. We need to bring those people into our cancer programs and make them part of our team. Train them up. And let them improve the health of our communities."

Group 4. Discussion revolved around innovative ways to improve clinical trial accrual.

"We talked about using a hub-and-spoke model to enroll more diverse patient populations in clinical trials. We agreed that there are likely deserts in this country where clinical trials aren't even available, where patients need to go outside their communities and possibly even to another state to participate. Smaller community sites within a geographic area could partner together in a model where 1 site offers breast trials, another site offers prostate trials, and a third site offers lung trials. These smaller cancer programs could come together and build a collective portfolio instead of 1 site trying to open a clinical trial for every disease site. Absent of an academic center in that same geographic area, these sites essentially create their own research network."

"We also talked about networking and mentorship opportunities between academia and community. Where the clinical trial process might get started at the academic institution and then transitioned back to a community program. We discussed decentralized trials where large research sites push out clinical trials throughout an entire network—not just 1 or 2 academic institutions. And centralized IRB is critically important to help smaller research programs get through all the regulatory requirements, or what I like to call the muckety-muck. Educational materials should be updated and culturally appropriate for all patients. Translated consent forms. That seems like it should be simple, but it's not. I have to go to my IRB, then a translator, and then back to the IRB to get it certified. It's a lot of time. Industry could help by developing a library of consent forms that are readily available—a tremendous time savings."

"We discussed how AI could solve the patient-matching portion of the clinical research challenge. AI technology for not just the prescreening but also the final screening of patients. There is a huge unmet need there in clinical trial matching. A tool to empower patients to participate in that process."

"While COVID-19 blew telehealth wide open, we have since retreated from this care delivery model. For example, the ability to cross state barriers and other exemptions have expired. But there are clinical trial-related tasks and/or procedures that community providers could complete so patients would not have to drive or travel to the academic center. Could some of the procedures be done closer to where patients live? We just need networking between the academic and community centers to identify opportunities."

"Finally, we talked about doing a better job of getting information on clinical trials out to the communities, whether that's through local events, churches, health fairs, or high schools, colleges, and trade schools. In essence, piggybacking on networks that already exist in the community and getting this information to someone who knows someone with cancer who would benefit from a clinical trial."

Closing Remarks

At the conclusion of these reports, 1 of the facilitators closed the deep dive by paraphrasing these words from Margaret Mead, "Never doubt the ability of a small group of committed citizens to change the world." He followed that with his own affirmation, "We are committed. We can do this. Go home and change the world."

PRECISION MEDICINE

New roles, like precision medicine stewards and navigators, are rapidly spurring adoption of precision medicine, bringing this care into all communities so that all patient populations may benefit.

Facilitators

- Sigrun Hallmeyer, MD; Medical Director, Cancer Institute and Cancer Survivorship Center, Advocate Lutheran General Hospital and Cancer Service Line
- Leigha Senter, MS, CGC; Licensed Genetic Counselor and Professor, Internal Medicine, Arthur G. James Cancer Hospital and Richard J. Solove Research Institute at The Ohio State University
- Emily Z. Touloukian, DO; Medical Oncologist and Hematologist and President, Coastal Cancer Center

Defining Precision Medicine

In the context of this discussion, facilitators defined precision medicine as treatments administered following the identification of a targetable alteration in the tumor or patient.

Why is Precision Medicine So Important?

Facilitators set this stage with this statement: "Targeted therapies improve survival and are often less toxic, resulting in a better quality of life for patients." For example, historically, patients with metastatic non-small cell lung cancer (NSCLC) have had poor overall survival with standard chemotherapy, with an overall survival of around 1 year. After the introduction of targeted therapies, overall survival more than tripled for a subset of these patients with NSCLC who had EGFR mutations and who were treated with tyrosine kinase inhibitors (TKIs).²¹ Another example of successful targeted therapy includes PARP inhibitors for patients with prostate cancer that has advanced and patients with breast cancer with a BRCA1 or BRCA2 mutation. These and many other data highlight the critical importance of precision medicine. Personalized medicine for nearly all tumor types has become standard of care for patients with cancer; indications are expanding and entering earlier lines of therapy. Yet less than 50% of eligible patients receiving next-generation sequencing (NGS).²² How can providers ensure patients receive testing to determine eligibility for these targeted treatments?

Operationalizing Precision Medicine

Busy providers are inundated with a wide choice of molecular tests and testing facilities. Some providers are contracted and must use a laboratory of choice. Even if the choice is up to the provider, there can be disagreement across providers on what tests and laboratories to use. How do providers make informed decisions?

Sometimes the answer is easy—for example, when there is a compendium test that the FDA has assigned to the approval of a certain drug, essentially tying that drug to a specific laboratory test. Providers who want to use that drug with a patient will then use that test to inform them if the drug is going to work for their patient. Unfortunately, that is not the case with most targeted therapies.

Instead, providers must understand the large group of actionable mutations—*PIK3CA*, *EGFR*, *BRAF*, and *NTRK*, among countless others—for which a drug has been developed and has become commercially available for targeted therapy and then decide what patients and where to test for these mutations. Providers must also understand the sample they need to send for molecular testing (eg, tissue, blood, saliva). Once providers identify the test they want to order and the laboratory they want to use, they must still navigate a complex order process that includes:

- An understanding of how and where to order the test (eg, is there a portal that providers must join by providing a National Provider Identifier number and other credentials, or, if the test is ordered by paper, how do providers track if the order was received?)
- Complex requisition forms.
- Specimen acquisition. Providers see many patients for second opinions, which means that patient specimens are often at another location, perhaps even outside of the provider's health care system; this adds even more complexity to molecular testing.
- Patient consent. Not only are these tests gathering genetic information that could have huge treatment implications, but there are also Health Insurance Portability and Accountability Act requirements and the need for cost discussions in case the test is not covered by the patient's health care plan.
- Payer coverage and/or financial assistance options.
- Physician signature process.

This complex decision-making process is 1 factor behind the slow uptake of molecular testing.

Front End Barriers and Best Practices

Identifying the *right* patient for the *right* test is still the biggest barrier for providers. With our competitive testing market, understanding the benefits and limitations of similar tests is cumbersome for providers. Currently, that decision is 100% a physician's function. Until EHRs can automate candidacy notification for specific molecular tests, oncologists and hematologists are making those decisions when they see patients in the clinic. But should oncologists make those decisions, or should molecular testing be a function of pathologists, who have much more expertise in handling this information? And should individual providers order molecular testing, or should the testing decisions be made by committee? Should next-generation sequencing (NGS) be ordered for every tumor at identified times so that oncologists seeing patients in clinic always have access to the most comprehensive information when choosing treatment? And how do providers improve testing? Is it up to the individual learner (provider) to keep up-to-date with patient populations who would benefit from certain tests, or is a more comprehensive approach needed in which decisions are made by consensus at molecular tumor boards or through national guidelines?

Another barrier is a lack of a navigation process. Successful precision medicine programs navigate patients through the testing process, which includes patient consent, patient (and physician) signatures, and cost discussions.

Best practice for molecular testing includes:

- Preparing order requisitions, including a way to ensure orders are filled out completely and accurately (correct test, correct specimen) to avoid treatment delays.
- Monitoring the molecular testing process to ensure the form was received, the laboratory is requesting a specimen from the correct pathology department, and the pathology department has packed and sent the specimen.
- Tracking. Did the specimen get to the laboratory? Where is the laboratory with processing? What is the estimated time of arrival on the results? Are there quality control issues that require new and/or additional specimens. Are there add-on orders?
- Retrieval of test results (ie, portal vs email vs fax).

Advocate Aurora Health employs an full-time equivalent (FTE) to act as a single point of contact (POC) for all precision medicine efforts. This nonclinical staff member supervises the entire molecular testing process from start to finish. All molecular testing requests are channeled through the POC, who has expertise with requisition forms and information requirements. In addition, this single POC:

- Has established personal contacts with all testing laboratories.
- Ensures that all patients fill out financial aid applications.
- Follows up on all testing, including retrieving specimens (blood, saliva kits) from pathology, the laboratory, or the patients' home; confirming that specimens have arrived at the testing laboratory; procuring updates on test progress and retrieving test result(s) from the laboratory; sharing test results with the ordering physician; and then scanning test results into the EHR.

Once test results are entered into the EHR, physicians interpret the results and report back to patients.

Back End Challenges and Quality Assurance Opportunities

Once molecular testing is complete, one of the common challenges is that most EHRs do not store the results in discrete fields—at least not yet. Molecular testing results usually come back to the provider as a PDF, which is then scanned into the EHR. Often, the molecular testing results are labeled differently, making it difficult for providers to find them in the EHR.

Once the molecular testing results are located and interpreted, providers must then answer the question, "How do these test results apply to patient care?" Testing results need to support appropriate therapeutic decision-making. Based on these molecular testing results, is the patient appropriate for a clinical trial?

In addition, testing results are automatically released to patients. This is a good practice in some ways, yet without upfront discussion about the molecular testing, patients get their results, call the provider, and ask questions, often with concerns about hereditary issues that may or may not be relevant. Molecular testing reports are generally not written in patient-friendly language.

Another challenge is interpretation and reporting differences between testing laboratories; these differences can lead to seemingly discrepant results. This variation impacts the ability and capacity to build clinical decision-support tools (eg, best practice alerts). If testing laboratories do not report results in the same way (eg, staff at 1 laboratory label

"I'm a well-trained oncologist, and
I know how to take care of my
patients. But this [precision medicine] is
not what I learned in medical school, and
it is extremely challenging to pick up this
knowledge in clinical practice as we go
to meetings like ASCO and participate in
discussions like what we are doing here
today [at #AMCCBS]."

a result "pathogenic," but those of another laboratory do not), essentially AI tools are rendered somewhat useless due to lack of a naming convention.

Variant reclassification, while often clinically relevant, can also be a burden on clinical staff. In addition, infrastructure is needed to reevaluate all evidence available about the pathogenicity of a genetic variant while considering any new evidence made available since the previous interpretation.

The potential for incidental germline findings is another challenge. What happens when the molecular test is performed in a patient for 1 purpose, but the test identifies an unexpected abnormality that is not related to the initial reason for doing the test? These findings can be surprising to both patients and providers.

Developing quality assurance opportunities to meet the above challenges is key. These opportunities include:

- Developing a standardized process to ensure molecular testing is being conducted equitably (ie, molecular testing is performed in all patients deemed appropriate).
- Setting up a standardized documentation process for molecular testing and its results.
- Implementing standardized labeling of molecular testing results in the EHR.
- Establishing laboratory and system partnerships for reporting and flagging patients for whom action is needed.
- Collaborating with tumor registry and practice analytic teams to streamline the molecular testing process.

Large Group Discussion

After the series of facilitated presentations, participants took part in open discussion and a question-and-answer session on what is happening in practice, challenges and barriers, and ideas and solutions to

"Most molecular tests
that are ordered give providers
more information than they need
at that particular moment. There's
always a little nervousness around,
'I am going to find out all of these
other things that I wasn't
looking for."

"I am a research nurse.

Some clinical trials will only accept certain NGS results as part of the documentation of getting patients enrolled.

So, 1 study will take this molecular testing result, and another study will require a different molecular test. And then trying to get back in touch with providers can be challenging. But physicians are the only ones who can make these decisions, and so everything just keep getting delayed."

meet those barriers. This discussion has been captured below.

The Cost of Providing Personalized Care

One participant asked how Aurora Health's single point of contact salary is funded and whether there is some way of getting reimbursed for these services. After learning that the physician practice absorbs the cost of this FTE position, the participant expressed concerns about this model's replicability, since many cancer programs and practices are not in the position to fund this type of FTE.

Financial navigation was suggested as the best model to look to when implementing a single POC to help providers navigate molecular testing. Financial navigation is another service that is not yet reimbursed by payers, but data have shown that FTE financial navigators pay for their salaries through cost-savings (eg, reduced denials and uncompensated care) and the downstream revenue they bring to the cancer program. Advocate Health expects to realize similar benefits from the work done by the molecular testing POC (eg, saving providers from ordering the wrong tests or having results sent to the wrong laboratory). With the many potential pitfalls in the testing process, elimination of these problems and the streamlined process and workflow developed by the POC ultimately are expected to save the health care system time and money.

"This might sound a little cheesy, but the reason I come to work is to give the best possible care to my patients. And that's where precision medicine really comes into play: the right patient at the right time with the right test is what all providers strive for. That 1 FTE is a worthwhile investment to achieve that goal."

There was consensus that much of health care is uncompensated time, but that it is the cost of providing care. There was recognition that payers are looking at chronic care management codes, principle illness navigation services, and other ways to reimburse for some of the uncompensated care provided. But, as a participant pointed out, "The work must be credentialed. And not everyone doing this work has a credential behind their name.

"Time is money. As a participant shared, "Time is a significant barrier to molecular testing and retesting. Sometimes a patient can't wait 5 to 6 weeks for results. We've tried to work with our health care system to block biopsy time for cancer patients so that I can order a biopsy, and it's done within a week. And they did that for a time, and then it stopped, because the health care system doesn't bring in revenue on open biopsy slots."

Guidelines and Standardization of Care

With the rapidly evolving field of precision medicine, use of guidelines and institutional pathways help ensure providers stay up-to-date with the latest medical and scientific advances.

At Advocate Health, providers were able to rally around <u>standardization of oncology care</u> through adoption of Via Oncology pathways (now <u>ClinicalPath</u>). These types of pathways and resources, like the <u>National Comprehensive Cancer Network (NCCN) Guidelines</u> and the <u>ASCO Clinical Practice Guidelines</u>, help cancer care teams make decisions at the bedside that are driven and supported by precision medicine and, often, AI. These decision support tools enable physicians to have the knowledge at their fingertips to develop life-changing, targeted, and personalized treatment plans.

As a participant shared, "And while some believe that [standardization] is rubber stamping cancer care, having been in oncology now for more than 20 years, I see the benefits. Humans are creatures of habit; many physicians are going to do what they did last week, because it worked. There are patients who receive substandard care, because not all physicians are going to national meetings and [are] able to keep up with the latest, cutting-edge treatments."

The Importance of Reflex Testing

Reflex testing requires a pathologist to arrange for testing of the specimen at the time of diagnosis. There was discussion about the importance of reflex testing and ways that providers can best use this testing. Communication and a unified EHR is key.

"How can we reflex test in lung cancer? It's easy with breast cancer and initial diagnosis. Everyone gets ER (estrogen receptor), PR (progesterone receptor), and HER2 testing—no matter what. But with lung cancer, pathologists don't know staging when the biopsy is in front of them. So, pathologists don't know if they need to [perform a] reflex test. We need to figure out those issues and [ways] to put processes in place and establish pathways so that we can communicate that information forward. It's likely a little simpler if you work in a large health care system where everyone is on the same EHR. I am in a community practice; my pathologist, my radiation oncologist, and my pulmonologist are all in different practices. That's 4 different EHRs and 4 different practices trying to communicate about 1 patient. We need automation, leveraging AI to standardize processes so that information is not lost from 1 care setting to the next, and providers can act."

Another participant noted that the molecular landscape of tumors is not static. If a patient was biopsied at diagnosis and then went through 2 or 3 lines of treatment, providers should retest—especially when it comes to lung cancer—so the reflex testing process itself

becomes more complex.

Payer Roadblocks

Many participants wanted to discuss the elephant in the room—payers—and the roadblocks payers have put in place that have slowed the uptake of precision medicine.

"Why aren't we talking about the role of the payer? Blue Cross [and] Blue Shield of Louisiana is my largest payer, and it labeled NGS testing as experimental, which means that all testing requests require prior authorization. We are seeing delays of 5 to 15 business days, in general. And if you have a patient with an aggressive form of cancer, there is an impetus to get them started on any kind of treatment. The worst care scenario is when NGS testing comes back, and providers realize the patient was put on a treatment with no benefit. These are the struggles we deal with daily. We've tried to bring Blue Cross to the table with Caris [Life Sciences] and Tempus. Our payers say the panel is too large and costs too much money. And Blue Cross is unbending. So, while the technology is amazing, we are facing a lot of real-world challenges just trying to get the best treatments to our patients."

Another participant agreed, "These are artificial challenges we create for ourselves. We're not struggling because the technology isn't there. The technology is there. The patients are there. The tumor specimens are there. It's all this other stuff [like reimbursement] that creates these barriers and pitfalls. I am grateful for your comment that payers play 1 of the biggest roles in erecting barriers to care."

Industry participants agreed. "I worked at Foundation Medicine for many years. And payers told us there was no reason to run a panel testing 324 genes, let's say, for lung cancer when there are only 36 genes that will have a targeted therapy. We went back and forth for months—even years—with payers to cover a test, sometimes even after the patient passed. This was an experience I lived day in and day out. I hear the challenges that you are all sharing, and I agree [that] payers are 1 of the biggest barriers to getting this technology into the hands of every patient who would benefit."

EHR Integration

There was consensus among providers that the process of filling out testing forms needs to be streamlined and—even better—standardized. One participant succinctly summed up the issue, "What I'm hearing from everyone is that you are all using your EHR, so the ability to order tests directly through the EHR has got to be a key component. The idea of going to a separate portal or, worse, having to fill out a paper form is absurd. Why not just click a button in the EHR to order the test—regardless of the test or testing lab? And that EHR integration needs to be done first and foremost with Epic (since it's the largest) and then with Cerner, Flatiron, and the other community-based platforms. EHR integration alone would save providers so much time."

Providers in the audience agreed and expanded on the role EHRs could play in improving molecular testing. "The other component to that is providers need to know when to order a test. It shouldn't necessarily be a physician deciding that they are going to order a test. It should be the EHR that tells the physician a test should be ordered. There should be a dropdown in the EHR to inform providers, 'The patient is now at stage 4. NCCN guidelines call for molecular testing.

These are the commercially available tests.' And then we need to go 1 step further and get that testing data back into the EHR, with alerts and notifications when there is actionable data. I believe that it all goes back to the EHR."

One participant shared that he was part of his organization's genomic integration team and that it takes senior leadership buy-in to support the infrastructure to build this type of technology. "Some [testing] companies have made it a lot easier than others. It does take some effort on the part of your IT [information technology] team to get this technology operationalized, but, once it happens, it's like a whole new world."

Several testing vendors shared that they have decision support tools within their platforms to assist providers in picking the appropriate tests; many said they offer precertification assistance to providers, as well.

One provider countered with this statement: "The pushback I would give is that this information is lab specific. So that's only helpful if you do what my institution is doing—essentially marrying ourselves to 1 lab. And that is not the typical experience at most cancer programs or practices. Most use multiple testing labs, and that means multiple processes. Multiple contacts. Knowledge of which vendors offer which services. And so, while I appreciate your efforts, I believe that providers need to be involved at the front end when processes are developed instead of at the back end, having to now deal with different information from different testing laboratories. There should be a streamlined process for providers. That is why meetings like this [#AMCCBS] is so important. To bring stakeholders together to develop solutions that benefit all providers and all patients. We need to learn what tools are out there, how they are currently being—or, in some cases, not being—used, and how can we overcome those barriers."

A participant who worked in hospital data integrations brought up the concept of single source of truth (ie, data that everyone agrees is the real, trusted number). "I think it's remarkable that your organization chose to partner with 1 testing vendor. The problem we run into working with multiple testing vendors, and I will use the example of a patient with non-small cell lung cancer. If a patient is EGFR-positive with [an EGFR] T790M mutation, Tempus has a different test than Foundation Medicine. And what you lose is a single source of truth. When I speak to CIOs [chief information officers] about true integration, I tell them that without a single source of truth, you can't really have a tumor-informed assay, especially in the monitoring space. So that's what we're looking to solve. But a lot of institutions don't want to choose only 1 vendor, because they feel liable and that they are not giving freedom of choice to their oncologists."

Most participants agreed that the EHRs themselves can act as barriers to molecular testing. Most EHR platforms were not built to integrate with third-party systems; they were built as vertical siloes. Clinical pathways face similar challenges. "It's very hard to get data out [of an EHR] and even harder to write data in. EHR vendors need to agree on standards if they are going to offer interoperability with molecular testing vendors. We want to be able to build reflex testing into clinical decision support so that EHRs can trigger appropriate test(s). Otherwise, providers are up against limited IT resources. Hospital IT resources can't keep up with building different decision support rules for which reflex tests to order based on the latest medical

and scientific advances."

A participant who does EHR integration at Foundation Medicine agreed that 1 of the most common reasons for institutional pushback is the amount of IT resource burden on cancer programs. "Our EHR integration is not an upgrade; nothing needs to be done in Epic. There is a small amount of IT testing that we need to be able to do. It's about 10 hours of work over a 2-week period to set up online ordering and delivery of tests. But it's still a request that goes into a queue with all the other requests that require IT time and resources. And we've heard that's burdensome. The testing facilities are trying to make that process as streamlined and easy as possible for providers. I can only speak for Foundation Medicine, but we provide this service at no cost to providers. We don't charge anything for our labor and the software we use to get this process up and running on your EHR."

One participant recognized the efforts of the various testing vendors but noted, "The higher ups still have to give approval that these testing platforms can integrate with the EHR. Most importantly, contracts need to delineate who owns what patient data and where. There is so much pressure on the C-suite right now around issues like protection of patient data and effective use of IT resources. To be honest, I am not sure if molecular testing is their number 1 concern."

Another participant zeroed in on the price of integration. "It's the cost. Our cancer program offers something like 700 tests. And what they [vendors] want to charge us to be able to interface with all those tests and all those labs is cost prohibitive. A lot of times the barrier to providing the best possible care to our patients with cancer comes down to cost. That's the pink elephant in the room."

One participant suggested that the solution may require regulatory intervention. "We all want to cure cancer. And the technology and the targeted therapies are putting us ever closer to that goal. But how do you translate these advances to a provider in the room with the patient? That is really where the rubber meets the road. If we had a federally-regulated EHR and a unified health care system where everyone was using the same EHR so they truly talked to one another, I would not reorder a CT scan that was done just 2 weeks prior by another health care system. In my opinion, about a good third of our health care dollars is in waste and inefficiencies like duplicative ordering of tests and scans. We need bigger solutions as a country."

Diversifying the Testing Pool and Clinical Trials

One participant pointed out that—for better or worse—genomic data are about 80% from White male or female patients. The participant asked how oncology could help diversify genomic data, helping to ensure all patients access to this technology.

"Part of the answer is to make sure that we are testing diverse patient populations now so that these data then become part of our greater knowledge. There is justified mistrust about the large genomic testing endeavors we've conducted over the years. Even with all the back-pedaling [that] we are doing to try and catch up with these data, it remains a huge, huge, issue for oncology."

One participant from a laboratory testing facility talked briefly about challenges to kicking off a large study of approximately 100000 patients. "We recognize that we need to provide diversity in the population we are screening. We've engaged with large institutions, both integrated health systems and academic networks. One of the chal-

"Every time I hear a
provider gets an NGS test
result back—whether it's from
Foundation Medicine, or Tempus, or
Caris—and has to scan it into the EHR,
it makes my skin crawl. And someone
earlier talked about faxing in a lab
request? That's just crazy with
the technology that is
available today."

lenges we are facing is that some of our partners are not really set up to recruit diverse populations. These institutions have set ways and patterns for patient recruitment to clinical trials. It has to be a true collaboration between the academic institutions, the communities where these diverse patients live, and industry if we are truly going to increase accrual of diverse patient populations to clinical trials. We can set those goals and expectations for our own studies, but if our partners are not set up to deliver those patient populations—which we've been told takes a lot of effort—and we are not working towards the same goals, it will be challenging for all of us."

Clinical Trials and Molecular Testing

A participant asked how others are layering in clinical trials with molecular testing. "How are you differentiating from the alphabet soup you receive on the genomic report to know that a specific marker has opened up an opportunity for the patient to enroll to a clinical trial?"

Another provider offered these insights. "That is the bane of my existence. I spend literally hours in meetings trying to automate that process. We lose at least 50% of our patients who are eligible for clinical trials, because the physicians either don't think of the clinical trial when they saw the patient in front of them, they didn't think the patient would be eligible, or that they didn't even know that the trial exists and was available to them. When it comes to precision medicine, it is even harder. I have been a big fan of basket trials [ie, when a single investigational drug or drug combination is studied across multiple cancer populations], which have really brought the whole concept of precision medicine to the forefront. These trials have allowed us to group patient populations with specific alterations together, treat them with a specific regimen, and see if it makes a difference. And now we know what works and what doesn't work for a tumor. But we have had the hardest time matching patients with a genetic or a genomic alteration to a basket clinical trial, because physicians don't think of agnostic therapeutics [ie, a drug treatment used to treat any kind of cancer, regardless of where in the body it started or the type of tissue from which it developed] when they see a patient with breast, lung, or colon cancer in front of them. And because I am a physician, I am advocating for taking the physician out of this process. Historically, we are trained differently. We have a one-on-one mentality. Every patient is a different scenario. It's very difficult for us to think in broader terms. We need automated mechanisms to quickly see information on appropriate molecular tests and appropriate clinical trials. If we can figure it out for standard of care, we can certainly figure it out for clinical trials."

"Our institution has clinical pathways. When I put a new patient into our EHR, I give them a diagnosis. I stage the diagnosis. Then I click on a treatment plan, and it is linked to our clinical pathway. With the information that I have fed into the EHR, it will then channel me to first-line choice of therapy. If our institution has a clinical trial that aligns with this treatment option, it will be my first choice. That has been my work over the last year: to create that intersection in the EHR so that our clinical trials are fed into our clinical pathway, and I can easily see that there is an appropriate clinical trial for a specific patient. So, that's probably as good as it gets."

But even that solution has its drawbacks.

"Here's the problem. I have 20 minutes with the patient. So when do you think I do this? When the patient is long at home. It's 6:30 [pm]. I've seen all my patients, and now, I am finally able to get to my charts. I am going into the EHR and giving this patient a diagnosis. I'm developing a treatment plan. I'm contacting my whole team and saying we need a precertification and that I am bringing this patient back next week for a treatment plan. And now the EHR is telling me there's an available clinical trial."

"My administrators are saying, 'I don't understand why this process does not work for you?' And I tell them that it is not my workflow. I am not in the room with the patient when I am staging and developing a treatment plan. I am not on the EHR when the patient is in the room. So, do I really pick up the phone at 6:30 and say, 'I know what we talked about at 3:30, but now I have revised my opinion, and there might be a clinical trial option'? The devil is in the details. You can have all this wonderful technology and processes, but if the physician cannot use them, what is the actual benefit?"

"Here's what I want. I want to walk in at 8:30. I want to look at my clinic schedule. And I want my clinical nurse and research nurse to tell me that your 3:30 patient is a candidate for this clinical trial. And your 4:20 patient has shown disease progression on the CT scan; we don't have a clinical trial, but you should do genomic testing, because they may be a candidate for a new targeted therapy that was approved last week. I want to enable my clinical nurses and my research team to be my back filler so that I can be the doctor I want to be."

In response, a participant shared that whereas the process at her cancer program does not capture the patient in the above scenario (ie, an individual seen earlier in clinic), "We have weekly huddles with all physicians about their new patients who are going to be seen in clinic that week. We also have a multidisciplinary clinic every week where we look at each patient and decide whether they are a fit for a clinical trial. And sometimes I see the patient a day before or only an hour before the physician, but we are trying to be proactive in our

processes."

Yet it is not the new patients who are getting lost in the process. "My biggest issue is not the new patient; I have 60 minutes I can spend with a new patient. My issue is the patient who is on fourth-line treatment. I know this patient well. I know their daughter. I know the name of their dog. Now their disease is progressing, and I only have 20 minutes [with an established patient] to think about a clinical trial. Those are the patients we are losing, because they are not discussed in multidisciplinary conferences. They are silent in our systems. No pathologist saw that latest CT scan to tell me that I should order a certain molecular test. This is the problem we need to figure out. How do we best treat patients along the continuum of care? Genomic testing is fluid, and clinicians need to be able to adapt to that fluidity."

A participant from the community oncology setting shared that they conduct weekly screening of all patients for clinical trial eligibility. They also prescreen patients 24 hours before they come to clinic to make sure nothing was missed. This cancer program uses a clinical trials software scrubber that integrates with its EHR and alerts physicians prior to the visit that the patient is eligible for a clinical trial(s). The research team educates clinicians regularly about open clinical trials, embedding research staff at each clinic location to talk to and receive consent from patients while they are in clinic. "We focus our efforts around next-generation sequencing and immunotherapy, especially for patients who are on Medicare (dis)Advantage plans, because those payers are not interested in paying for that technology, and clinical trials are a wonderful way to get those patient access to cutting-edge therapies. Is it a lot of work? You bet. The people we employ to scrub our patients [ie, ensure that insurance claims for a patient are without mistakes that would lead to coverage denial]—

"I see 20 patients in clinic
daily. I have 20 minutes with a
patient to tell them, 'You have stage 4
disease, and you are going to die from this.
I am going to fight to make you live as long
as you can with this disease. We are going to
transform this disease into a chronic illness.
These are your treatment options. What's
it going to be?' And now I'm going to
introduce a clinical trial? The reality is
that would make me late for my
next 6 patients."

that's uncompensated work. But it is what we must do to provide the best clinical care to our patients."

One participant asked what was required on the front end to get patient data into the EHR so that it is able to be scrubbed. "One of the challenges we have when we try and pull reports out of the EHR is that every physician puts their staging in the EHR differently. Have you had to standardize physician practices? Or is that something your research team is helping with?"

The community provider responded, "Our physicians are busy providing care, so the clinical research staff cleans up the data on the back end. They put data where it should go [in the EHR] so that it is more identifiable and easier to locate. I'm not going to put that burden on the physicians; that won't go over well."

This solution is not without its drawbacks, with 1 participant sharing an inability to use scrubbing software due to red tape. "Ultimately, these solutions also need to work from an IT perspective, from a HIPAA perspective, and from a leadership perspective. Personally, I think these scrubbing technologies are fabulous. They are plug and play IT platforms that log into your EHR and quickly analyze your patient data—by physician, by day, by whatever parameters you establish—to assess eligibility for clinical trials. Fabulous. The latest reason my organization has given for saying, 'No,' is because it does not want the scrubbing platform to be oncology specific. Our organization does research in neurosciences and cardiology, etc. And if we spend that kind of money, our organization wants a platform that will look at all clinical trials."

Provider Education

One participant commented that more and more drugs are being used in the adjuvant and neoadjuvant setting, making screening even more important in both the oncology world and the community health care setting, which will require education and connection with providers in primary care, internal medicine, general practice, and medical specialties.

A provider in the room agreed. "Cancer screening does originate outside of oncology most of the time. My program brings in our primary care colleagues and educates them about NGS testing—why it is so important for patients to get this type of testing. This type of clinician-to-clinician education is especially critical, because screening rates have not yet bounced back to pre-COVID-19 rates."

Another provider pointed out that the education gap in precision medicine shares similarities with the challenge faced 10 years ago when immunotherapy was new. Smiliar to the strategy ACCC championed for the successful adoption of immunotherapy, this provider advocated for the need to bring together multidisciplinary teams to educate patients about the importance of molecular and genomic testing. "And my question to you all today is this: what role does the patient play? When oncology was overwhelmed by having to educate primary care and urgent care about the mechanisms of immunotherapy, we empowered our patients with tools like the ACCC immunotherapy wallet card to help with this education. Wouldn't it be great if a patient came to us and said, 'I have lung cancer, and you should be testing me for EGFR'? Any thoughts on that?"

The discussion then turned to new technology like <u>multi-cancer</u> early detection. "About 70% of cancer incidences have no routine

screening today. If, and when, screenings like multi-cancer early detection become [a] standard of care, clinicians may find those incidences of cancer that we are not even looking for today." This type of screening may help identify certain types of colon, breast, prostate, ovarian, and cervical cancers much earlier in the disease trajectory when they are easier to treat.

Patient Education

A participant wanted to know how providers are handling patient education about molecular and genomic testing. "A lot of people are afraid to get this type of testing. Patients want to know what is being done with that information. Coming from the pharma side, I see the benefit: we find another marker, and we can ultimately match a drug that can help. But many patients have different biases, and we need to get education out."

There was consensus about the importance of patient education, particularly for underserved patients and individuals other than White patients. One provider shared that it was rare for her to see a patient who does not want to have molecular testing done on their tumor. "Knowledge is power, and patients recognize that. I get much more pushback when we're talking about germline testing and genetic predispositions—not always how it will affect the patient who already has cancer but how it may impact the daughter who is sitting next to them in the clinic."

And germline testing comes with its own barriers. "Patients should not be punished for being diagnosed with cancer. But if you look at payer policies, all of them say that a patient can't get germline testing unless they've first had some kind of genetic counseling."

Most agreed that patients are more accepting of genetic and genomic testing now than they were 5, or even 10, years ago. "I have seen an evolution. It used to be that patients were worried about losing their insurance after germline testing. Now legislation protects against loss of coverage—although life insurance and long-term care disability are not protected. People are still worried about [with whom] providers will share this information...Patients are worried about the government, their health insurance company, and even their employers having access to this information. These concerns are not to be taken lightly."

Discussion around patient education included shared language and a 2016 white paper on consistent language around molecular and biomarker testing from the LUNGevity Foundation. Words matter. "Is it a biomarker? Is it a mutation? Is it a variant?... The genomics field has moved away from some of the terms. For example, we're not supposed to say mutation anymore, but we've come to understand [that is the term] patients want us to use. They understand and accept the term mutation. Shouldn't we ask patients first about the language they prefer?" There was consensus that shared language helps and allows everyone—patients, caregivers, and providers—to understand molecular testing and ways that it may impact treatment decisions. Tools like ACCC's biomarker lexicon can help guide these discussions.

One participant shared that he works for <u>CancerPath</u>, a new startup aimed at educating patients about biomarker testing so that they can talk to their physicians about getting tested. "We're trying to address 2 concerns. The first is to stop people turning to unreliable sources on the internet to get their health information. And the second is to ensure that patients receive the testing that can inform—and hopefully improve—their treatment decisions. We have the patient empowerment and education piece down. What we're trying to figure out is how not to antagonize physicians. How can we work with physicians and not seem like adversaries?"

A provider in the audience admitted that a culture shift may be needed on both ends. "Physicians and patients must understand and accept that physicians don't know everything."

Many providers in the room agreed with that statement. "I am just the doctor. And this is just another patient in my day. But to the patient, this is their life. We [physicians] need to recognize that patients are fighting for every week, every month, every year. We [physicians] need to humble ourselves and remember that we are here to serve the patient." Another participant shared, "For an oncologist who treats every kind of cancer, it has become nearly impossible to stay current with every single practice-changing publication. But there is nobody more motivated to learn about their disease than the person who is affected by it. As much as I am a very compassionate oncologist, I am not personally affected by the disease in the same way my patients are. I want to empower that motivation. Give my patients a playbook. There are many 1- to 2-physician practices that are drowning—financially and from patient volume—and 1 way we can help these physicians is by empowering patients with knowledge and education."

A participant asked the physicians in the room how they react when a patient comes in asking for a specific test or even a specific therapy.

"It's a 2-edged sword. Because sometimes what the patient wants is completely ill-advised. But I am a huge proponent of education, education, education. I would much rather have that problem and discuss with a patient why that test or that therapy is not appropriate for them than miss a conversation with a patient that prompts me to look or think about treatment differently."

And what about when patients agree to molecular testing and do not see a benefit? "We have a trial right now looking at how providing a patient education video about tumor genomic testing at the time of ordering translates to patient outcomes. Our prior data suggest that there is a drop off in trust in their provider if patients have genomic testing, and it does not result in a therapeutic change. This knowledge is important, because it can help improve patient education and patient-provider communication."

One provider stated that she has experienced exactly this scenario. "I go into a room, and I'm introducing the concept of molecular testing of the tumor. I'm excited about investigating their tumor tissue, because I could find something truly life changing. The reality is that this patient is in their fourth-line therapy, and now I have to throw out the big net of NGS testing. But first I must explain that big net to the patient. And then at their next visit, I tell them that I have found nothing. That really weighs on the patient-provider relationship. The patient asks, with all of the technology they see on TV and this talk about personalized medicine, why I don't have something to offer them?"

Other providers shared similar experiences. "I've stopped testing everybody, because I was so dismayed by the lack of results that were actionable, by the promise that I come to the bedside with and, ultimately, just disappoint my patient."

One provider started framing patient discussions differently. She tells patients that whereas targeted therapies are becoming more common, and cancer treatments are becoming more individualized, only a very small number of patients have these mutations. "My patients hear [that] from the get-go and are not automatically thinking they will have 1 of these actionable mutations. I tell my patients that if they have 1 of these mutations, there are really good treatments out there, and that's why I am testing. It's important to frame the discussion, but it takes longer than 20 minutes. While patients will hear what they want to when they're in the room, patient education is so important."

Even with this low incidence, many in the room expressed support of broad testing for all patients with cancer. "Payers ask, 'Do you really need a 360-panel test?' And the answer is, 'Yes, we do if you want to ensure [that] patients with low incidence mutations get the best possible care.' Ultimately, we need to get to the understanding that every patient should have the broadest test possible. But someone still must pay for that kind of testing. And so, like we've shared previously, cost is a huge barrier."

Yet the promise of molecular testing is clear. "We have enough targeted drugs that are tumor agnostic that we should push forward with making sure that genomic testing is offered to every cancer patient," noted a participant. "The collective knowledge that comes from that testing is infinite."

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