
Artificial and Business Intelligence Technology
EHR Integration: A Key Component of Precision Medicine
2024 Trending Now in Cancer Care Part 2
Payer, Manufacturer, and Supply Chain Challenges and Opportunities
Key Partnerships in Research and Clinical Trials

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From 2010 to 2019, the Association of Cancer Care Centers (ACCC) fielded an annual Trending Now In Cancer Care Delivery survey to its membership to gain insights into challenges faced and—most importantly—to devise solutions to address those challenges. Members shared that during and after the COVID-19 pandemic, they did not have the time and/or resources to take this annual survey. This led ACCC to identify alternative ways to collect these data. In 2023, ACCC hosted a series of interactive sessions at its 49th Annual Meeting & Cancer Center Business Summit (AMCCBS). Insights and solutions from these discussions were used to develop the 2023 Trending Now In Cancer Care Part 1 and Part 2 reports. In 2024, ACCC hosted a second series of interactive sessions at its 50th AMCCBS. Insights and solutions from these discussions can be found in 2024 Trending Now In Cancer Care: Part 1 and Part 2 below.

ARTIFICIAL AND BUSINESS INTELLIGENCE TECHNOLOGY

Emerging technologies like machine learning, generative AI, and natural language processing have great potential for improving the cancer care experience, addressing inequities in health care access and treatment, and impacting point of care. To achieve this potential, health care providers and administrators must promote safety and quality during implementation, ask the right questions to protect patients and staff, and effectively evaluate a wide range of technology platforms and vendors.

Facilitators:

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AI: A Practical Orientation

With the rise of AI tools like ChatGPT, terms like machine learning, generative artificial intelligence (AI), and natural language processing are being thrown around frequently. And while considerable overlap exists between AI and natural language processing, these terms are often used interchangeably even though there are distinct differences between them. AI is a broad category that encompass machine learning, deep learning, and generative AI. Natural language processing and large language models have contributed to some of the recent advancements in AI and machine learning, but there are unique aspects to natural language processing like rules-based methods of parsing text that are distinct.

It is critical that oncology professionals understand these concepts and their applications in cancer care. According to a 2023 Medscape survey, 80% of physicians surveyed said that they believed it "very important to become educated about AI and its applications in the medical workplace."[1] In that same survey, physicians were asked how they are currently using AI in medical practice; the top 3 responses were to research conditions, to use electronic health records (EHRs), and to accomplish administrative tasks (**Table 1**).[1] A 2024 survey found that 1 in 3 researchers are now using ChatGPT at work.[2]

Generative AI is just 1 facet of this emerging technological landscape, but it is undeniably 1 of the most popularized and widely available tools to date. Closely related to tools like ChatGPT is the concept of a language model, which is a probability distribution over a sequence of words. When provided with sample text,

Table 1. How Medical Practices Already Use AI[1]	
Researching conditions	13%
Working with EHRs	10%
Accomplishing administrative tasks	10%
Scheduling patients	9%
Scheduling staff	8%
Summarizing a patients EHR before visit	8%
Communicating with patients	7%
Diagnosing conditions	7%
Using examination room conversations to generate clinical note	6%
Predicting a patient's prognosis	5%
Treating patients	5%

language models predict the probability that any word will follow it. These models can be used to generate text—a common example is autocomplete—as well as brand new content as provided by ChatGPT.

ChatGPT stands for *generative pretrained transformer*. Pretrained machine learning models are equipped with foundational knowledge that allow them to classify the sentiment of a review or flag an abusive message. In a clinical context, these models can also predict metastatic disease and extract adverse events from charts. Part of the appeal with pretrained models is that you can use 1 model to do many different things. There's generally a tradeoff for quality of work, however, as traditional machine learning models built with a singular purpose in mind tend to do their tasks better. Still, there are ways to improve the performance of pretrained models by finetuning them on labeled examples to supplement their foundational knowledge.

The transformer is a type of deep-learning architecture that was developed at Google in 2017; transformers trained on the internet using sites like Wikipedia and Reddit that house massive amounts of information. This virtually unbridled access to data allows transformers to continually advance and grow their knowledge base. But a pretrained model requires human intervention to constantly refresh its knowledge base by providing new information in real-time.

Opportunities to use AI and machine learning in oncology include:

- Extracting key variables from unstructured documents
- Summarizing visit notes from an audio recording (ambient scribes)
- Predicting treatment response
- Suggesting treatment regimens
- Discovering new molecular targets
- Generating documentation.

That said, it is important to consider broad challenges that accompany this technology, which include:

- Validation of the output of machine learning models
- Hallucinations (models inventing answers)
- Biases
- Data shift.

With these challenges in mind, it is more important than ever for health care professionals to carefully validate the quality of models, because high-quality data are essential for use of any of these types of AI and machine learning algorithms.

Elevating Excellence: Assessing Patient Safety and Quality in AI Applications

How do we ensure safety and quality when applying AI in health care? Within the broader technological culture, there is a history of prioritizing innovation and speed over safety in the creation of digital products. This mindset has led to a culture in which safety and quality are not prioritized. Instead, these are treated as secondary outcomes.

Although consumer-facing digital technology has not had an ideal track record for safety, digital technology in health care generally evaluates and prioritizes both patient safety and clinical quality quite well.

AI is currently at the peak of its hype cycle, which reflects the overinflated expectations placed on it throughout 2023 and into 2024. Therefore, this is the time when we should be thinking about safety and quality over rapid innovation. Primary quality concerns related to AI in health care include the following:

- Maintaining data accuracy and integrity
- Potential bias leading to inequity
- Having the good judgment to use these products safely.

There is fairly universal agreement that regulation is necessary for AI. An executive order on safe, secure, and trustworthy AI was

> "What happens if a model is learning based off data that's not inclusive, and we're coming up with decisions and conclusions that are really only relevant for a subset of the population and should not be applied to the broader population?"
>
> – 2024 AMCCBS ATTENDEE

released by the White House in 2023. Moreover, a new Health Data, Technology, and Interoperability (HTI)-1 rule outlines the process through which EHRs and other software companies become certified by the Office of the National Coordinator for Health Information Technology.[3] These companies must show that their technology meets a set of very specific requirements in accordance with the US Department of Health and Human Services in order for their product to be released. Legislation like the HTI-1 rule is a necessary attempt to understand where AI fits into EHRs and other health care-related software.

Legislation goes hand in hand with appropriate skepticism on the part of health care professionals, providers, and administrators who need to understand the basics of these tools and the questions they must ask to ensure quality and safety. To evaluate potential AI solutions, providers and administrators should consider the following:

- *Understand the use case.* Who is meant to use this technology? For what purpose? Understand the overall risk of the workflow that is getting enhanced by AI. Will it affect administrative tasks, scheduling or prior authorization, treatment decisions, or diagnosis?
- *Understand the data that are training the AI.* Ask questions about where the data is coming from and what—if any—data quality standards are in place.
- *Find out how the model is refreshed.* How often is the data set evaluated for accuracy and refreshed to ensure up-to-date recommendations? In health care in general and oncology specifically, science and treatment regimens are rapidly changing.
- *Find out how quality and safety concerns are addressed.* Are there specific teams that will evaluate the quality of the tool? If so, how?
- *Understand the implementation plan for the tool.* Who will be trained? How will appropriate use of the tool be ensured?

Above all, providers and administrators need to be proactive with providing guidelines about how to use AI and ensuring that their staff understand the limitations and appropriate uses for this technology.

The potential for AI is broad, but health care professionals will likely first implement it for repetitive administrative tasks that can quickly lead to burnout, thereby freeing up providers to focus on more meaningful tasks and patient interactions. AI can also fill in gaps by improving operational efficiencies and remedying staffing shortages in some capacity. But there will likely be a healthy amount of skepticism around allowing AI to make high-level decisions regarding treatment.

Cancer programs and practices struggling to keep up with the latest AI advancements and how to best implement this technology in practice can start by asking certain questions:

- How is your program or practice evaluating AI tools?
- As you evaluate AI tools, what workflows do you want to support?
- Has anyone adopted an AI tool that is helping to drive success at your organization?
- What are your main concerns when it comes to adopting new AI tools?

Applying Technology in the Community Oncology Space to Address Health Equity

To ensure that a technological investment is worthwhile, it is essential to clearly identify and understand the problem being solved rather than jumping at the chance to try out every new AI tool on the market.

John Sargent and Amogh Rajanof Vantage Health Technologies learned the importance of having a clearly defined problem when they began building out a technology platform that allowed them to ingest and analyze data, create prescriptive and predictive recommendations from that data, and link back to workflows. They knew that this platform was powerful enough to manage nearly 10% of the world's population on antiretroviral therapy, but they quickly realized that no one was actually using the dashboards they built because they were complicated, packed to the brim with complex data, and generally overwhelming to navigate.

This finding led them to experiment with natural language generation and chatbots to help describe and simplify the information in the dashboards and satisfy the need to interpret massive amounts of data. They also went on to build more sophisticated predictive models and machine learning models to aid in management decision-making such as determination of patients most likely to stop taking their medication or reasons that a certain 5 of 1000 hospitals are doing poorly.

> "All people should have a fair and just opportunity to live a longer, healthier life free from cancer regardless of how much money they make, the color of their skin, their sexual orientation, gender identity, disability status, or where they live."
>
> – AMERICAN CANCER SOCIETY[4]

Shifting its attention to the US in particular, Vantage Health found social determinants of health to be a major barrier to its vision of helping all people prevent, find, treat, and survive cancer. Findings included the following:

- Unaddressed social determinants of health are linked to 60% of premature deaths.[5]
- Some 50% of the American public have at least 1 social determinant of health issue.[6]

- Social determinants of health cost the US economy $93 billion annually in excess health care costs.[7] In addition, social determinants of health disproportionately affect minorities and economically disadvantaged people.[8]

Vantage Health faced additional challenges related to a shortage of nurses, social workers, and health care professionals and widespread burnout in the wake of the COVID-19 pandemic. To combat these barriers, Vantage Health partnered with Oncology Consultants, the largest independent oncology practice in Houston, Texas, to help cancer patients with suboptimal outcomes. Vantage Health was drawn to the practice's HOPE (Holistic Oncology Patient Equity) initiative, which offers social navigation services to anyone undergoing cancer treatment with the goal of improving value, equity, and experience for patients and health care outcomes. With its own money and resources, Oncology Consultants started hiring community health care workers to identify potential issues with patients, to screen patients, and to help resolve any issues. The HOPE initiative's biggest challenge was that it was primarily managed on paper using basic tools, which made the project limited in scope. Oncology Consultants looked to its partnership with Vantage Health to provide technological solutions.

> "As a nurse, I have always believed that addressing whole-person needs for patients is the right thing for humanity. We believe that Vantage Health can help us prove that it's the right thing for business too."
>
> — SUSAN SABO-WAGNER

Vantage Health identified the following key barriers in the practice's HOPE Initiative:

- Social determinants of health that disproportionately impact patient outcomes
- Racially, linguistically, and culturally diverse patient populations with complex and unmet needs
- Limited resources to identify address social determinants of health needs in patients
- A reactive, limited paper-based approach that limited the overall effectiveness of the initiative
- A lack of analytics to support workforce orchestration and to manage multi-payer contracts at scale.

Vantage Health went through the process of clearly identifying the problem, the desired output, and patient outcomes before diving into the technology. It then broke the company down into 3 roles (executive, operations and management, and patient navigation) and the information that the individuals in those roles need to know on a daily or weekly basis. Only then did Vantage Health set out to add automation and AI into the mix.

Vantage Health identified the following output objective: To maintain an average physical and mental Healthy Days score of 20 for all participating patients. It also identified 3 process objectives:

1. To screen 100% patients for social determinants of health needs
2. To ensure that 100% of social determinants of health needs identified are fulfilled
3. To ensure appropriate reimbursement for all qualified patients.

This approach let to the development of ***Social Health 360***. The first use case centered around a social worker who had a patient navigator role. Vantage Health framed the data for the social worker so that the next best actions to take for each patient could be determined. It started with collecting patient-centric data with a wide range of cultural and socioeconomic nuances, which help to deliver better care to the patients. Based on the data collected and the problems identified, the social worker was guided toward interventions needed to be delivered for the patient(s). As soon as the interventions were delivered successfully and the patient outcomes were met, a new tool was delivered: a Healthy Days Electronic Patient Reported Outcome (ePRO) Tool. The tool contains 4 simple questions:

- How many days did you experience that were physically unhealthy?
- What was the severity?
- How many mentally unhealthy days did you experience?
- What was the severity?

This measure provided a number that social workers could easily compare month over month to track changes. The outcomes of this patient navigation tool included:

- A person-centric assessment that captured social, cultural, and linguistic nuances around patient needs
- Assessment data that drives next best actions to support patients
- Healthy Days ePROs that measured the longitudinal impact of navigation support on patient outcomes.

The second use case followed a nurse manager in a supervisory role and sought to provide information that would help supervisors determine what they could do to prevent burnout on their team and to ensure that their team reached their program and process objectives. In Social Health 360, AI identified social workers in real time who were overburdened and then neatly summarized its findings into a few sentences to immediately bring it to the supervisor's attention. The outcomes of this supervisory tool included:

- Bite-sized weekly insights that helped supervisors understand how they could support their team of navigators
- Staff-specific plain-English insights configured to improve performance while managing burnout.

The third use case involved an executive director of clinical strategy in an executive leadership role. At this level, leaders need to know how their program is performing on a weekly basis, whether or not they need to hire more staff, if they are seeing high patient caseloads across social workers, and what action they need to take from an executive perspective. Instead of requiring these executives to log into a system, Social Health 360 used natural language processing technology to summarize those insights and deliver it via email. With this executive tool, Vantage Health identified the following:

- Before intervention, inequities were identified in Black and Vietnamese patients. After addressing social determinants of health needs for these patients during intervention, a significantly better Healthy Days ePRO was reported by patients (44% increase for Black patients and 61% increase for Vietnamese patients over a 3-month intervention period).
- There was a clear return on investment for providers, including increased Healthy Days ePRO scores across Black and Vietnamese patients and the entire patient population.
- Timely access to key benefits for the most impacted patients improved.
- Studies conducted by Humana validated improvement in Healthy Days as a short-term proxy for cost savings and reduced inpatient admissions.
- Increased satisfaction and efficiency were communicated by users through anecdotal feedback.

Vantage Health identified the following future plans for the practice:

- *Workflow automation.* Generative AI to transcribe patient calls and auto-populate patient forms and notes will be leveraged to reduce the burden of documentation and manage staff burnout (can save about 30-45 minutes).
- *Personalized social care.* AI and machine learning models and methodologies to inform personalized social care workflows will be leveraged to improve the patient experience and promote healthy behaviors. One potential use case for this technology is to leverage data collected about health literacy, patient loneliness, and Healthy Days ePROs and to implement predictive models to identify patients who are more likely to be nonadherent based on those data. Providers can then develop a person-centric approach that is tailored to those patients' needs. In practice, this solution could segment patients into social care workflows based on the level of care they are likely to need.
- *Patient self-help.* An AI-driven navigator will be used to reduce a patient's over-reliance on patient navigation staff. Further, access to need-based care navigation services to patients will be enhanced; it is intended to empower the patient as they navigate online health care tools.

The question "How can AI help my organization?" will generate 1 million answers. Staying grounded in the problem at hand is necessary to ensure that an organization will arrive at the best-fitting solution(s).

Evaluating AI and BI Technology Solutions

With the wide array of AI and business intelligence (BI) solutions marketed by vendors, it is important to learn how to prioritize the following areas of need before buying a new piece of technology:

- *Where are your highest risks, and will this solution help them?* Typically, patient populations, administrators, and providers make up this category.
- *What processes are causing staff burnout?* Adding more and more clicks to a process can be a huge burden for a provider trying to take care of a patient. During interviews with patients, detailed discussions can be documented by AI without a person having to do the manual work. If there are data like a provider or a nurse workflow that need to be documented in several places, they may be managed with use of an AI and/or BI tool.
- *What can improve the safety of patients and staff?* This solution may look like a tool that can analyze a patient's entire health-related history, age, and social determinants of health and then use those data to help providers to decide on the right medication and treatment at the right time for the right patient. Alternatively, this solution may look like a tool that can predict potential adverse events that a patient may have based on medical history, social determinants of health, and other historical factors.
- *How can staff be assisted to work at the top level of their license?* An example of this solution may be a tool that takes repetitive documentation tasks from the plates of providers and staff. These repetitive tasks may be delegated to machine learning, or a robotic process automation that creates workflows to remove these tasks from providers and put them in a tool.

The next factor to consider in evaluating AI and BI vendor solutions is the type of technology that may best benefit an organization:

- *Interface.* An interface in computer science refers to a shared boundary of 2 or more separate components of a computer system as they exchange information. It can be between software components, hardware devices, or a combination of both.
- *Automation (robotics).* Software robots (bots) are programmed to mimic human actions to perform repetitive tasks like data entry, data extraction, or form processing.
- *Machine learning support.* This subset of AI focuses on the development of algorithms and models that enable computers to learn and make predictions or decisions based on data.
- *AI.* This branch of computer science creates systems or machines capable of performing tasks that typically require human intelligence.

The purchase of any new technology requires an analysis of return on investment (ROI). To quantify ROI, identify the time involved or the error(s) saved and multiply them by the technology's per-unit cost divided by the total cost of the technology or application. Other factors to consider when measuring ROI include:

- Analysis of startup costs vs ongoing maintenance costs
- Definition of mutual goals and risk sharing between the health care organization and the vendor
- Consideration of a trial period based on quantifiable objectives
- Knowledge of ramp-up costs.

BI and the Bottom Line

Oncology programs and practices continue to struggle with recovering missing reimbursement and dealing with burdensome prior authorization processes, diverse payer plans with varying fee schedules, cost reductions for claims processing, and more. A 2022 *Oncology Issues* article shows how business intelligence platforms are being used to perform revenue cycle tasks best suited to automation and freeing business and revenue staff to tackle issues that require human intelligence and intervention.[9]

Health care organizations must also ensure a good understanding of their high- and low-value tasks. For each task, question whether it is generating revenue or saving costs. Does the task reduce inefficiencies, create safer patient environments, and/or mitigate risks? Do the efficiencies gained outweigh the cost of the tool or platform?

It is also crucial to not just measure a singular objective (eg, time saved), because that time savings goes hand in hand with worker satisfaction. When a patient navigator or provider can spend less time on a tedious administrative task, they can use that time to create more value for their organization.

Health care professionals should be enthusiastic about AI and BI technology solutions. But they also should be skeptical—especially of widely available tools like ChatGPT. These professionals must formulate and ask pointed questions to ensure that quality and safety are kept at the forefront of new advancements. OI

EHR INTEGRATION: A KEY COMPONENT OF PRECISION MEDICINE

In oncology, some of the most pressing challenges in precision medicine include consistently low biomarker testing rates, patients' tendency to fall through the gaps and miss out on opportunities for targeted therapy, and a lack of data harmonization within the electronic health record (EHR).

Facilitators

- **Sigrun Hallmeyer,** MD, medical director, Advocate Lutheran General Hospital Cancer Service Line; medical director, Advocate Lutheran General Hospital Cancer Survivorship Center; codirector, medical research, Advocate Aurora Health
- **Jonathan Katchmore,** associate vice president, Commercial Diagnostic Strategy, Loxo@Lilly
- **Christopher McNair**, PhD, associate director for data science, director of cancer informatics, Sidney Kimmel Cancer Center; assistant professor, Department of Medical Oncology, Thomas Jefferson University
- **Brian Davis,** genomics implementation lead, Epic
- **Nate Wade,** PharmD, MBA, BCOP, associate director, clinical oncology, Flatiron

Level Set: 2023 Precision Medicine Deep Dive

Dr. Sigrun Hallmeyer began with a brief review of the 2023 Precision Medicine deep dive held at the ACCC 49th Annual Meeting & Cancer Center Business Summit. Challenges and solutions from these discussions were captured in 2023 Trending Now in Cancer: Part 2. Similar to last year and for purposes of this discussion, facilitators defined "precision medicine" as treatment administered following the identification of a targetable alteration in the tumor or patient. All agreed that precision medicine continues to expand exponentially, from prolonging life to saving lives; precision medicine is now considered standard of care for people with cancer.

However, several challenges remain to successfully delivering precision medicine in clinical care. The clinician is the pivotal point for administering and interpreting testing, as well as connecting the patient to the therapy they are qualifying for based on the positive test result. This means the clinician must constantly understand which diagnosis, line of therapy, and test(s) are appropriate for each patient's unique case. For physicians who have been practicing for decades, this technical knowledge was not part of their initial training, so being at the center of these critical decisions can be overwhelming.

The process of ordering tests also presents challenges, as it involves many hurdles for busy clinicians to work through, including the following:

- Navigation of third-party lab and testing portals
- Complex requisition forms
- Specimen acquisition
- Patient consent
- Physician signature process
- Financial aid and coverage assistance options.

"From the moment the physician actually knows *what* [test] to order, *when* to order, *where* to order, and *how* to order, they still need to think about patient consent, the signature process, and the financial costs," said Dr. Hallmeyer. "It's not just the physician and the nurse and the patient, it's actually an entire system that needs to be created around ordering precision medicine for your patient."

Each patient's case has its complexity, from requiring written consent to navigating the financial process of paying for tests that can cost upward of $1000 to $2000. Patient identification and process navigation are also key factors, including preparing the requisition, monitoring the processing of the order, ensuring the specimen is sent to the right laboratory, facilitating test result retrieval and documentation, and discussing results with patients and caregivers. And that's just the front-end processes.

Several back-end issues exist as well, such as the fact that most EHRs do not store genetic or precision medicine results as discrete data fields. Instead, that information is often buried in a PDF, making it difficult to find and inhibiting clinician support. Other pertinent back-end issues include the following:

- Test interpretation and determination of which results will provide truly actionable information
- Automatic EHR release to patients
- Application of results, including appropriate decision-making, moving forward with clinical trials, and responding to incidental germline findings.

Dr. Hallmeyer then discussed the high value precision medicine offers, as it can identify subgroups of patients who will benefit from targeted treatment. The overall survival benefit can add years to the life of a patient with targetable mutations, whereas others can potentially receive a curative outcome from an otherwise deadly malignancy. Therefore, it is important to understand which test to order, when to order the test, and how to implement that information into clinical practice.

However, treating the right patient at the right time with the right test remains difficult—nationally and globally. Data show that many patients still fall through the gaps because they are not being tested. Those tested and found to have a positive result are often not connected to that result and ultimately do not realize any benefit from therapy. Therefore, the need to optimize the precision medicine ecosystem is clear.

Precision Oncology Landscape

"In precision oncology today, approximately 47% of patients with advanced non-squamous non-small cell lung cancer have a driver mutation targetable by an FDA approved agent," shared Jonathan Katchmore, associate vice president, Commercial Diagnostic Strategy, Loxo@Lilly. As an example, he pointed to the 10 actionable biomarkers that exist for non-small cell lung cancer. Data also show that precision-based therapy can lead to improved survival vs systemic therapies.

Many tumor types have FDA-approved targeted therapies, including therapies that target genomic biomarkers regardless of the type of solid tumor. The number of actionable biomarkers is rapidly growing, so providers face the challenge of constantly keeping up to date with new information. In 2000, only 17% of oncology trials included biomarkers, but by 2018, that number climbed to 55% and continues to grow.[10] According to Katchmore, in oncology, 86 percent of prostate clinical trials, 74% of melanoma clinical trials, and 69% of breast cancer clinical trials are exploring biomarkers (**Figure 1**).[10] Trials have also emerged around pan-tumor biomarkers (eg, MSI and NTRK), reflecting the interest in biomarker-defined cancer indications.

However, according to a study conducted through The US Oncology Network, biomarker testing rates remain low; only 46% of patients in a real-world setting with advanced non-small cell lung cancer were tested for actionable biomarkers with FDA-approved therapies.[11] Another study in 2019 demonstrated that even after targets were identified, only 48% of patients with non-small cell lung cancer and an actionable driver went on to receive the associated targeted therapy.[12]

Multiple practice gaps contribute to low uptake of precision medicine. According to a 2022 study from the Precision Medicine Coalition, "Patients are lost at various steps along the precision oncology pathway because of operational inefficiencies, limited

Figure 1. Tumor Types Exploring Biomarkers in Oncology Clinical Trials[10]

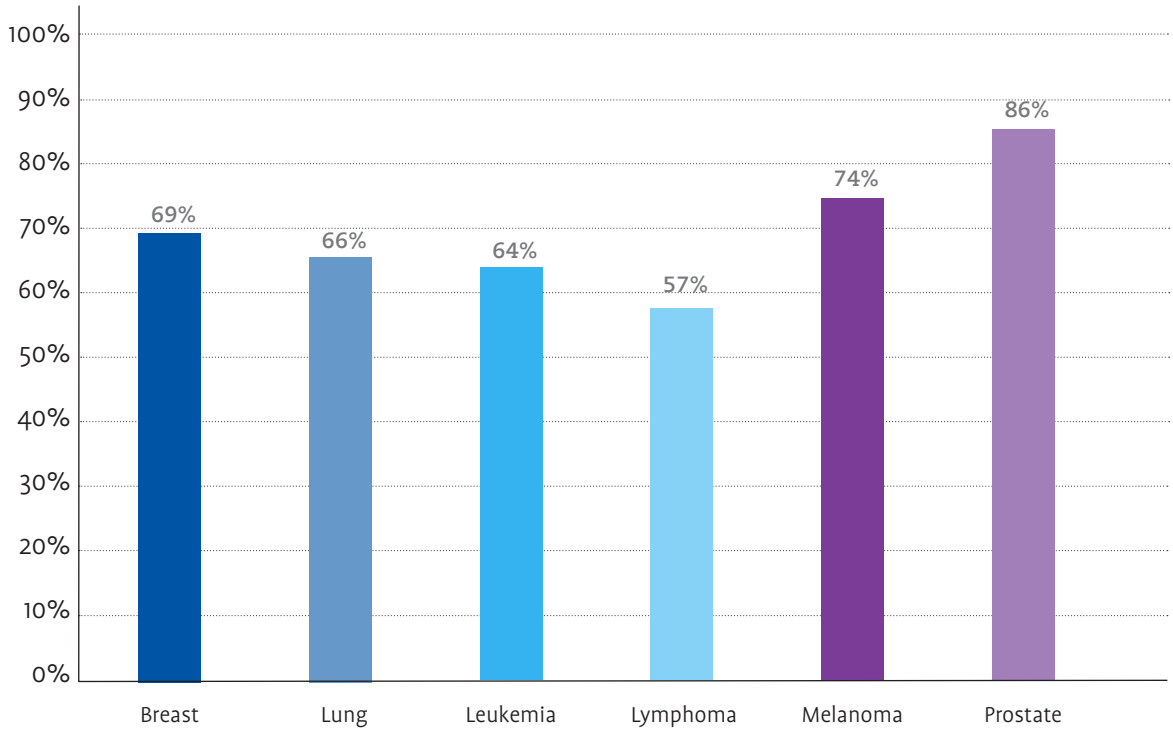
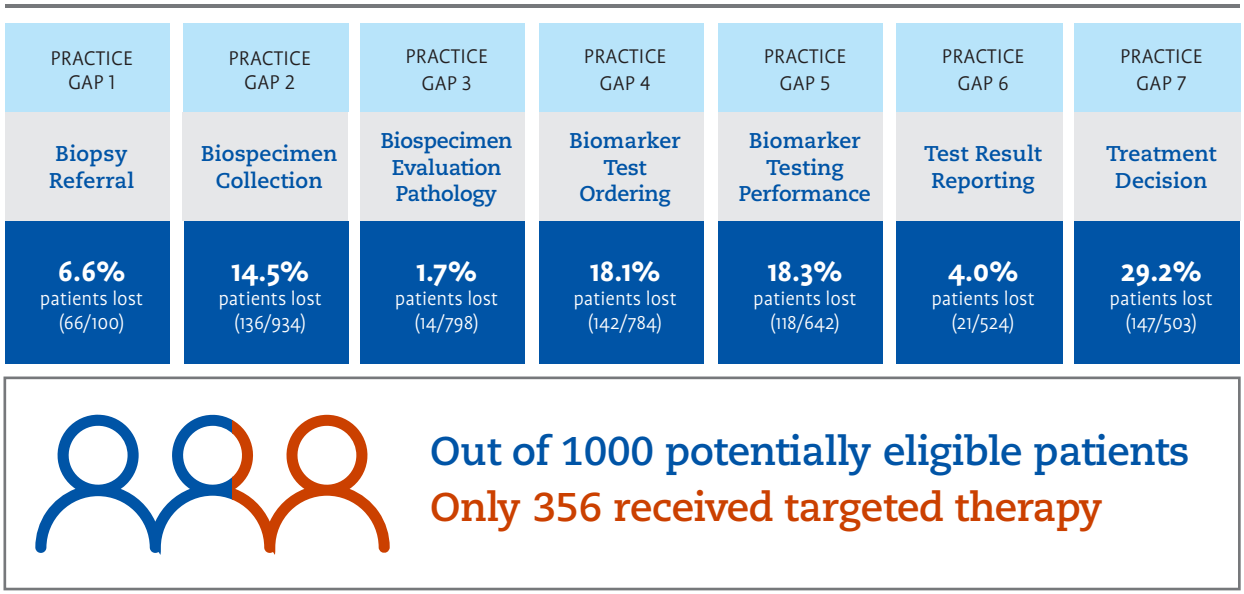


Figure 2. Impact of Clinical Practice Gaps on the Delivery of Precision Oncology[13]



understanding of biomarker strategies, inappropriate testing result usage, and access barriers."[13] Specifically, Katchmore pointed to data that showed 142 of 784 patients (18.1%) were lost at the stage of biomarker test ordering and 147 of 503 patients (29.2%) were lost at the treatment decision stage (**Figure 2**).[13] The result of failing to order biomarker testing and failing to ensure that patients found to be biomarker positive go on to receive the associated targeted therapy is that hundreds of potentially eligible patients miss the chance to receive highly effective targeted therapies that are less toxic and have fewer adverse effects associated with them.

So, what can providers do today to improve those percentages? Employing a multidisciplinary approach to care will improve communication and patient outcomes by closing clinical practice gaps and mitigating and solving existing challenges and barriers. A 2020 study found that molecular tumor boards can help treatment teams navigate the complexity of delivering precision medicine to patients with cancer through the following:[14]

- Multidisciplinary input
- Expert review process to evaluate and implement molecular testing methods and optimize testing workflow
- Guidance for clinicians on interpreting test results
- Determination of therapeutic options for patients with genomic alterations
- A common goal to optimize precision medicine recommendations for patients with cancer.

Another 2020 study published similar data that showed how a molecular tumor board can expand the population of patients receiving precision medicine.[15]

Real-World Experiences in Precision Medicine: Sidney Kimmel Cancer Center at Jefferson Health

With no central repository for generated genomic information and a constantly evolving medical landscape, some chaos is inherently embedded in the molecular testing process, admitted Christopher McNair, PhD, associate director for data science and director of cancer informatics at the Sidney Kimmel Cancer Center. And while there is no "one-size-fits-all" solution for molecular testing, EHR integration is key to success. McNair went on to discuss how Jefferson Health used EHR integration to support its precision medicine program by:

- Standardizing genomic profiling across the enterprise
- Ensuring consistent workflows between clinic sites within the health care system about which patients to test, when to test, and how to interpret the results
- Expanding the number of patients who receive genomic testing to decrease disparities in care.

To accomplish these goals, Jefferson Health set out to standardize the vendors used by integrating diagnostic ordering and results into the EHR system across different testing modalities, including solid tumor profiling, liquid, germline, and disease-specific testing. McNair emphasized the importance of creating a well-rounded team to support a precision medicine program, encompassing the following areas:

- Medical, radiation, and surgical oncology teams
- Pathologists
- Researchers
- Clinical trialists
- EHR representatives
- Information technology (IT) staff.

Read more in the February 2024 blog entitled "Building a Precision Medicine Team: EHR Integration for Timely Biomarker Testing,"[16] where ACCCBuzz interviewed McNair and Jennifer Johnson, MD, PhD, FACP, associate professor in the Departments of Medical Oncology and Otolaryngology and co-director of Jefferson Health's Precision Medicine Initiative.

When putting together the team, consider creating the role of a ***precision medicine steward***. With the proper support and infrastructure from a cancer program or practice, precision medicine stewards can improve operational processes, increase efficiency, navigate patients and providers through the testing process, and help to remove barriers so all eligible patients are appropriately tested.

In a recent video, ACCC members shared highlights from their journey to streamline precision medicine testing processes and improve the patient biomarker navigation experience through the addition of precision medicine stewards.[17] Astera Cancer Care in New Jersey[18] and Sanford Health,[19] the largest rural health system in the US, with cancer programs in North and South Dakota and Minnesota, shared with ACCC how they implemented and now use precision medicine stewards in their cancer programs.

Other details to consider include recruiting individuals with access to leadership to ensure institutional alignment, forming a committee whose diversity reflects that of the cancer program, and keeping decision makers at hand to streamline EHR integration later in the process.

With so many testing modalities available and multiple vendors within the same modality, it can be overwhelming for a precision medicine program to know where to start. McNair "recommended following the path of least resistance." In practice, this means recruiting individuals at the institution who are outspoken and have the authority to move through the approval process quickly. Partnering with experienced vendors or those with the least complex workflow is also helpful.

Another key consideration in piloting a precision medicine program is developing a reproducible process. Coming to the table with a fully formed plan can help the process run smoothly and set up the program for success for the second, third, and fourth EHR integrations. In addition, it is helpful to understand what is most important to the decision makers in the room and highlight the most salient reasons to accomplish EHR integration, such as the following:

- Physician time saved
- Order visibility
- Potential liability
- Clinical trials
- Research opportunities.

There are also multiple options for EHR integration. Point-to-point integration requires individuals to build the data roads themselves, whereas EHR-managed integration allows individuals to use existing data roads. For cancer programs and practices choosing EHR-managed integration, McNair shared Jefferson Health's scoring rubric for vendors, which highlighted the following information as important to decision-making:

- Cost and coverage
- Materials required
- Testing for DNA, RNA, whole exome, PD-L1
- Testing analyses
- Details available to the user
- Turnaround time
- Interactive interfaces vs static reports
- Physician decision support, including clinical trial availability
- Data integration with the clinical record
- Ability to review larger data sets in aggregate (research collaborative)
- Data accessibility for research purposes
- Molecular tumor board support.

In preparation for its first EHR integration, Jefferson Health's precision medicine committee began setting up meetings with potential vendors to collect the relevant data for the scoring rubric. Rather than spending time taking extensive notes, asking clarifying questions, and scheduling follow-up meetings to capture all this information, the committee developed a precision medicine vendor intake form in REDCap. Vendors were required to complete this form before meeting with the committee, making it easy to gather all the necessary information and prioritize vendors to move forward with.

IT involvement is critical, with the first step being to understand the organization's process for EHR integration. For example, there will likely be a set of committee-based approvals with various requirements, such as security questionnaires with forms to complete, technology reviews, and departmental review processes. These additional steps may require input and information from vendors, so keeping contacts readily available is useful. McNair advised deploying persistence and patience throughout the process—as IT often has competing priorities—and documenting the process to streamline future integrations.

"It's interesting to see how different organizations are approaching precision medicine operationally and making sure there's a governance structure around it... These new roles are popping up, like a precision medicine navigator. It's not just an alert at the point of care that can ensure the patient gets tested. It's also somebody on the backend ensuring patients don't fall through the cracks."

–AMCCBS ATTENDEE

After completing the first EHR integration, solicit feedback from committee members and the vendor; track metrics; and identify areas of greatest impact by collecting data from physicians, researchers, and patients. Jefferson Health, for instance, saw increased testing, decreased time required to order testing, and more patients being vetted for molecular-driven clinical trials. Tracking metrics before and after the EHR integration is also useful in demonstrating the quantitative value of the efforts made. Jefferson Health collects the below metrics from all its vendors during an EHR integration:

- Order numbers
  - Geographic location
  - Disease type
  - Ordering physician
- Number of quantity-not-sufficient specimens
  - How many are immunohistochemistry only?
  - How many are reflex to liquid?
- Turnaround time
  - Time from order placed to results provided
  - Time from order placed to specimen received at the testing site
- Financial information
  - 14-day rule triggered orders
  - Cases denied by insurance
  - Number of patients who were approached for additional information for coverage
  - Additional coverage offered by the company
  - Metrics for total out-of-pocket payment from patient.

These data are compiled into a vendor-agnostic genomic data warehouse that researchers and physicians can access, simplifying the process of deciding *which* patients to test and *when* because the necessary information is already built into the system. This solution helps ensure eligible patients are not left out of testing opportunities.

McNair then spoke to the need for a scalable way to automate as much of the testing process as possible, using the ability to track all the available data to identify which patients are not being tested to improve health equity. McNair admitted that it is challenging to keep up to date with new hospital system purchases of different EHRs and the constantly evolving nature of available integrations. Despite the long and difficult process of EHR integration, McNair said the benefits to physicians and patients are clear.

Benefits of EHR Integration: The Epic Perspective

Brian Davis, genomics implementation lead at Epic, offered attendees an overview of Epic's genomics module, explaining that this module created "a place for genomic data in the EHR…It's essentially liberating genomic data from the PDF and giving it a discrete place within the EHR so that you can treat it just like any other clinical data." Davis reported that nearly 70 organizations have gone live with Epic's genomics module, and this number is increasing annually by nearly double digits.

Davis then went on to discuss how Epic is helping providers realize the 3 main benefits of EHR integration: greater provider efficiency, clinical decision support, and data harmonization.

> "EHR integration means not having to go into the web portal of various labs, but [providers] being able to stay in the EHR to work."
>
> –2024 AMCCBS FACILITATOR

As an example of improvements in ***provider efficiency***, Davis pointed to a 2022 study from the University of Pennsylvania that found EHR integration reduced time spent ordering by 75% (2 vs 8 minutes) and time spent managing genetic test results by 80% (1 vs 5 minutes).[20]

Addressing the second benefit, ***clinical decision support***, Davis admitted that "There's a lot of challenges for us [related to] Epic not being a content vendor for decision support…But I think there's some things that will happen in the future to make clinical decision support easier to provide." To generate clinical decision support content, Epic will have to either go through a third party—where there might be a paywall—or through physicians and specialty steering boards. "Our customer providers can help us generate some of that clinical content, but it's a labor-intensive process and it's time consuming," Davis shared. "And I think this is probably the area where there's the most to be gained if we can figure out a better way to do this [provide clinical decision support]." One of the actions Epic is considering is to manage some clinical decision support content on its cloud. "We are working with some of our content vendors to put decision support in the cloud so it's not something that groups [providers] have to manage themselves," explained Davis. "It's something providers can call and retrieve. And Epic can manage these data centrally. We're looking at options."

The third benefit, ***data harmonization***, is also a bit of a moving target but Davis assured attendees that data harmonization is happening naturally. "Aura is our specialty diagnostic platform. It's a module that labs purchase and install themselves." For participating laboratories, Aura provides an out-of-the-box way to receive orders and send results in a fraction of the implementation time required to configure a traditional point-to-point interface with providers and health systems.

Davis shared information about Epic's genomics brain trust and urged Epic customers interested in participating in this monthly meeting to reach out to him. "At that brain trust, we've been talking about data harmonization a lot in the last year…about the benefit of using coding systems. There are coding systems for genomic variants—although there's some opinions about which coding systems are better than others," explained Davis. "If the variant that's coming

back has a specific ID and you compare that ID to something like ClinGen or ClinVar, it could be extremely beneficial for clinicians and researchers. The problem is the labs and their willingness to send those coded identifiers. But we're working on that."

As more providers and lab organizations start digitizing genomic data, the need for data harmonization becomes clearer. To that end, Epic built its data structure based on the standards for genomic data created by HL7 (an interoperability body) in 2017 and has since added more data fields.

> Ultimately, I think it still requires a clinician to make the decision. Is this testing appropriate? Because the result will affect the treatment choices that I can offer this patient... I'm wondering if what we're trying to do is force a square peg in a round hole, where we're trying to force a technical solution to what is ultimately a process and payer perspective problem."
>
> –AMCCBS ATTENDEE

Current Solutions and Opportunities in Precision Medicine: The Flatiron Perspective

Nate Wade, associate director, clinical oncology at Flatiron, first described the company's flagship product, ***OncoEMR***, an oncology-specific EHR used by about 2900 clinicians at about 800 care sites. Flatiron also developed molecular profiling integrations, with more in development, that can be used by community practices that lack the extensive resources found at larger institutions. These molecular profiling integrations aim to make the ordering process more efficient and test results more actionable and easily retrievable. However, for results to be stored and interpreted consistently by computers, they must be harmonized across all the various vendors. Practices achieved the following customer outcomes with these integrations:

- More than 75% of qualifying tests are ordered using the integrated workflow
- Eighty percent of orders are submitted in less than 5 minutes
- Two days' faster time-to-treatment on average for patients with non-small cell lung cancer.

Wade then introduced ***Flatiron Assist***, a clinical decision support platform that reviews patients' characteristics (eg, disease, biomarker status, and stage) and recommends all National Comprehensive Cancer Network concordance regimens appropriate for that patient. Flatiron Assist also has robust reporting capabilities to determine who uses the tool and additional layers for payer or practice preferences.

The last tool discussed by Wade was Flatiron's ***OncoTrials***, a clinical trial matching tool born out of physicians' need for information regarding clinical trial availability in real time, while the patient is with them in clinic. This tool allows physicians to screen patients for available clinical trials before their visit. Flatiron's molecular profile integrations enable this capability, as they eliminate manual biomarker entry by letting the structured biomarker results flow directly into OncoTrials.

Looking to the future, Flatiron has identified the following opportunities to help support precision medicine efforts:

- Importing biomarker results straight into OncoEMR and Flatiron Assist to reduce the burden of manual entry
- Identifying patients for appropriate testing
- Better reporting capabilities within the EHR
- Tools to alert physicians of new opportunities for patients.

At the conclusion of Wade's talk, Dr. Hallmeyer opened the session up for discussion, asking how providers can empower patients and caregivers to be an active and educated part of the molecular testing process. Participants discussed the difficulties that arise when patients have access to test results via their patient portal before their provider even has a chance to review and interpret them. "I can tell you exactly when a patient received a Tempus [test] result within our EHR because I get a portal message. But there's a ton of stuff [in the report] that's positive, right? And a ton of stuff that's negative. It's even hard for me to interpret, let alone for the patient," said Dr. Hallmeyer. "What are we doing to help our patients understand all those data and how they apply to them?"

While attendees agreed with the concept of full transparency with patients and that lab results should be released as soon as they are available, they also agreed that a provider should be the one to review that report with patients. To help patients navigate this complex environment, group consensus was that patient portals should provide information about what to expect and what questions to ask their provider at their next appointment. This information would help bridge the gap between full transparency of results and the ability to understand and interpret results with the provider's help.

PAYER, MANUFACTURER, AND SUPPLY CHAIN CHALLENGES AND OPPORTUNITIES

Oncology providers continue to face numerous challenges in their quest to provide quality, equitable care for all patients with cancer, including excessive and overuse of payer authorization policies; federal provisions in the Inflation Reduction Act that may negatively impact prescription drug prices and drug price negotiations between manufacturers and the government; challenges with patients on Medicare Advantage plans; and ongoing drug shortages.

Facilitators:

- **Nicole Tapay**, JD, director, cancer care delivery and health policy
- **Tricia Neuman**, ScD, senior vice president, executive director, Program on Medicare Policy, KFF
- **Tom Kornfield**, founder and CEO, MAST Health Policy Solutions
- **Alti Rahman**, MBA, MHA, CSSBB, chief strategy and innovation officer, American Oncology Network
- **Kirollos S. Hanna**, PharmD, BCPS, BCOP, FACCC, director of pharmacy, Minnesota Oncology; assistant professor of pharmacy, Mayo Clinic College of Medicine
- **Jorge J. García**, PharmD, MS, MHA, MBA, FACHE, assistant vice president, Oncology, Infusion and Investigational Drug & Research Pharmacy Services, Miami Cancer Institute, Baptist Health South Florida

Impact of Prior Authorization: Patient and Provider Perspectives

Prior authorization remains one of the most discussed barriers to timely quality cancer care delivery among health care providers.[21] The negative impact that this cost containment strategy has had on providers and patients is well documented. A 2022 survey of American Society of Clinical Oncology members found "that nearly all participants report a patient has experienced harm because of prior authorization processes, including significant impacts on patient health such as disease progression (80%) and loss of life (36%). The most widely cited harms to patients were delays in treatment (96%) and diagnostic imaging (94%); patients being forced onto a second-choice therapy (93%) or denied therapy (87%); and increased patient out-of-pocket costs (88%)."[22] In 2023, of the 1000 physicians surveyed about the effects of payer authorization by the American Medical Association:[23]

- 94% reported delays in care.
- 93% reported a negative impact on patient clinical outcomes.
- 78% reported patients who abandoned treatment.
- 19% reported adverse effects for patients that led to avoidable hospitalizations.
- 13% reported life-threatening events or interventions to prevent permanent impairment or damage.
- 7% reported adverse effects that led to patient disability or permanent bodily damage.

In response to these challenges, on January 17, 2024, the Centers for Medicare & Medicaid Services (CMS) finalized the CMS Interoperability and Prior Authorization Final Rule (CMS0057-F), establishing requirements for certain payers to streamline the prior authorization process, including:[24]

- Payers must provide notice of the prior authorization decision within 72 hours of expedited requests and within 7 calendar days for standard requests.
- If a request is denied, the specific reasons for denial of the prior authorization request within that decision time frame must be outlined.
- Aggregated prior authorization measures must be publicly reported on websites.

Unfortunately, this rule only applies to payers in select federal programs and does not apply to the "approximately 158 million Americans who are insured through their employment—the most common kind of coverage in the United States."[25]

Prior authorization requires providers to engage with a combination of tools, both analog and digital. While e-prior authorization tools can streamline workflows, provider data such as documentation of medical necessity and adherence to guidelines are key to obtaining authorization from payers.

Robotic process automation is another tool in the provider arsenal that can help streamline the prior authorization process. Numerous vendor solutions are available to collect patient and procedure details,

> "We're getting closer to a world where employers are going to want to start understanding value-based care agreements...because they're just not seeing the value that's being delivered from a payer perspective. And prior authorizations are supposed to be delivering that [value]."
>
> – AMCCBS FACILITATOR

populate forms accurately, and forward forms to the appropriate payer, eliminating manual paperwork, expediting the process, and reducing potential errors.

As our health care system continues to move to a value-based care delivery system, alternative payment models like bundled payments, episodic payments, and capitation have the potential to reduce prior authorization requirements.

One attendee commented that prior authorization is deeply embedded in payers' business models as a revenue generator; therefore, payers are resistant to providers attempting to eliminate or streamline prior authorization. On the other side of the issue, employers are starting to use the price transparency data available to them, and they are demanding to see the value in cost savings that prior authorization was promised to provide.

Impact of White-Bagging: Patient and Provider Perspective

Drug spending is the largest cancer expenditure, and it continues to grow. In 2020, the US pharmaceutical spend was $535 billion, with a projected 5-year growth rate of 39%.[26] In addition, the number of new cancer cases and outpatient service volumes are expected to rise in the coming years. Payers continue to organize around cost containment to ensure they can meet their budgets through a variety of tactics, including formulary exclusions and white- and brown-bagging policies. In recent years, payers have adopted the practice of clear bagging or dispensing a patient-specific medication from a provider pharmacy under common ownership to the provider's office, hospital, or clinic for administration.

While many cancer programs have policies in place that prohibit brown bagging due to chain of custody, patient safety, and liability concerns, white-bagging can also have a negative impact on cancer programs in the following areas:

- Chain of custody
- Drug stability
- Fragmentation of care
- Electronic health record (EHR) and automation incompatibility
- Charge integrity
- Lack of compensation for provider services to receive, store, compound, coordinate patient visits, re-dispense, administer, and handle waste
- Hindered point-of-care treatment decisions
- Increased provider liability.

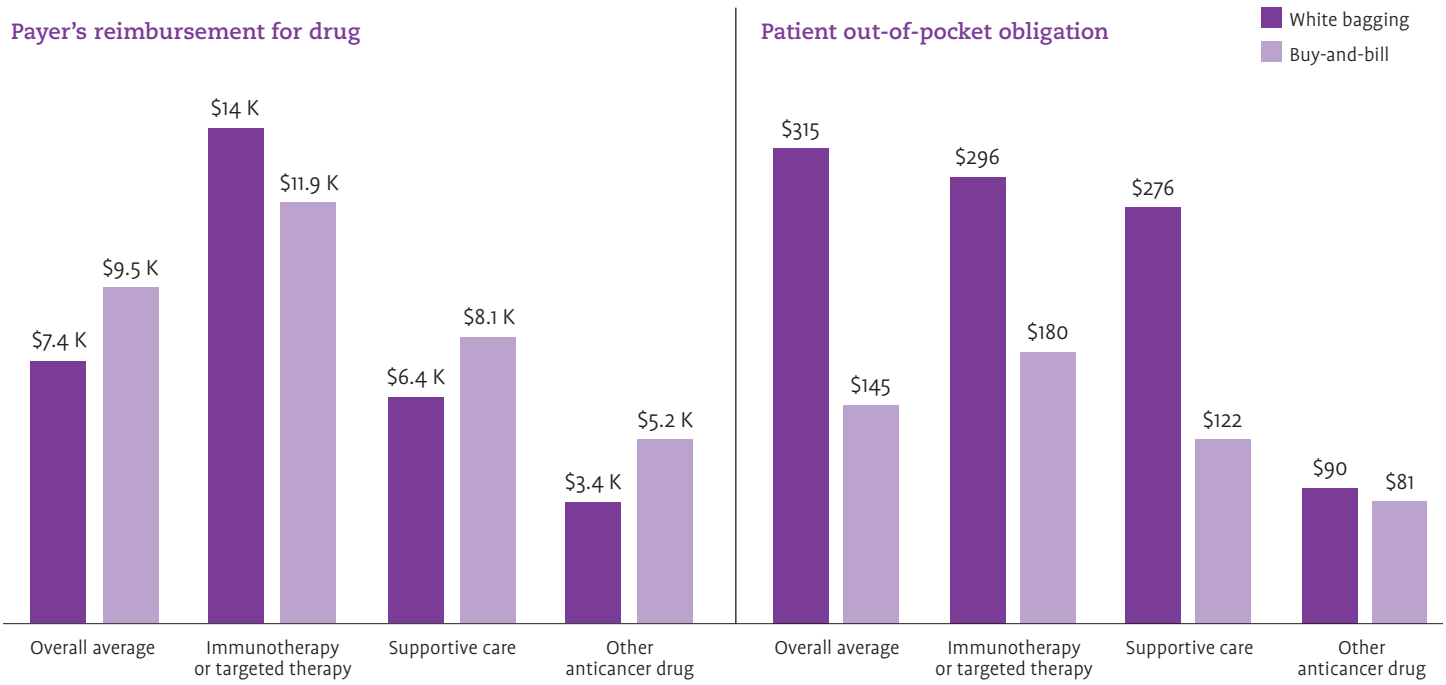
A 2021 Vizient study surveyed 268 providers across the nation; they reported the following top issues regarding white- and brown-bagging policies:[27]

- 95% reported that they experienced operational and safety issues
- 83% reported that the product did not arrive on time for patient administration
- 66% reported that the product received was no longer correct due to updated patient treatment course or changed dosage
- 42% reported that the product delivered was an inappropriate and/or wrong dose
- 43% reported that the product was not built into the computer system
- 37% reported that the product delivered was damaged.

Another study from *JAMA* examined the financial outcomes of white- and brown-bagging oncology drugs among privately insured patients with cancer.[28] The study included 50 cancer drugs with the highest spending in 2020 based on the Medicare Part B spending dashboard. Of the 113076 patient-drug pairs, 53.1% were immunotherapy or targeted therapy, 27.6% were supportive therapy, and 19.3% were another type of anticancer drug. Interestingly, the study found that on average, payers paid $2000 less for white-bagged

> "One of the things we've started seeing in the last 3 to 4 months is that payers are requesting that we prior authorize not only the chemotherapy drugs, but also the supportive care drugs separately, which means separate identifying numbers....It's very time consuming and slows down getting the authorization and getting patients' treatment started."
>
> – AMCCBS ATTENDEE

Figure 3. Payer Reimbursement and Patient Out-of-Pocket Obligation for Oncology Drugs, White-Bagging vs Buy-and-Bill, 2020[28]



Source. Tina Shih YT, Xu Y, Yao JC. Financial outcomes of "bagging" oncology drugs among privately insured patients with cancer. *JAMA Netw Open*; 2023;6(9):e2332643. doi:10.1001/jamanetworkopen.2023.32643

oncology drugs, but that patient out-of-pocket costs were higher for white-bagged products vs buy-and-bill products (**Figure 3**). In other words, payers are not passing these cost savings on to patients but are instead increasing their profitability.

The Inflation Reduction Act and Its Impact on Patients With Cancer

In recent years, Americans have become increasingly concerned about prescription drug costs. According to a 2023 poll from KFF:[29]

- 83% of adults see pharmaceutical profits as a major factor contributing to the cost of prescription drugs.
- 31% of adults say that in the last year, they have not taken prescription medicines as directed because of costs.
- 28% of adults say it is difficult for them to afford to pay for their prescription drugs.

For years, Congress has faced strong opposition from the pharmaceutical industry for its attempts to lower prescription drug costs, despite the bipartisan support for several policies that eventually became part of the Inflation Reduction Act of 2022, including:

- Limiting how much drug companies can increase the price of prescription drugs each year to no more than the rate of inflation
- Allowing the federal government and private insurance companies to negotiate with drug companies to get a lower price for prescription drugs for people with Medicare
- Placing a limit on out-of-pocket costs for seniors, such as co-payments for prescription drugs.

> If we [providers] don't figure out how to bring care to the home, someone like Amazon will. Disruptors like Amazon continue to acquire more primary care, and with that comes a lot of control with referrals. Now providers are thinking more actively about this group of competitors. How are they organizing? They have the big power of benefit design, and we [providers] don't get to design benefits."
>
> – AMCCBS FACILITATOR

Another motivation for the passage of the Inflation Reduction Act is the increase in Medicare spending, both past and projected, which concerned policymakers. The following provisions in the Inflation Reduction Act were implemented in 2023:

- Drug companies are required to pay rebates if Medicare drug prices rise faster than inflation.
- Monthly cost sharing for insulin products was limited to $35 for people with Medicare.
- Reduced costs and improved coverage for adult vaccines in Medicare Part D, Medicaid, and the Children's Health Insurance Program were implemented.

Future provisions that will be enacted between 2024 and 2026 include:
- In 2024, Medicare Part D out-of-pocket spending will be capped at about $3300 for brand-name drugs.
- In 2025, Medicare Part D out-of-pocket spending will be capped at $2000.
- In 2026, negotiated prices for 10 high-cost Medicare Part D drugs will take effect.

One of the many benefits of this act is that it will drastically lower out-of-pocket costs for enrollees that use expensive cancer drugs. Based on Medicare spending in 2021, the Part D out-of-pocket limit is expected to lower costs for more than 1 million people with Medicare coverage.

Tricia Neuman of KFF then described the timeline for negotiated drug prices, as outlined by the Inflation Reduction Act. In 2023, the secretary of the US Department of Health and Human Services (HHS) selected 10 drugs from a list of 50 negotiation-eligible drugs with the highest total Medicare Part D spending and Medicare Part B spending. This list of negotiation-eligible drugs excludes the following:
- Drugs that have a generic or biosimilar available
- Drugs less than 9 years (for small-molecule drugs) or 13 years (for biological products) from their FDA-approval or licensure date
- Certain small biotech drugs (from 2026 to 2028), drugs that account for Medicare spending of less than $200 million in 2021, and drugs with an orphan designation as the only FDA-approved indication.

After the HHS secretary sends the initial price offer to the relevant drug companies, the latter have 30 days to respond. When this article went to press, HHS had not yet published the maximum fair price for the first 10 Part D drugs that go into effect in 2026. The number of drugs subject to price negotiation will accumulate over time, adding 15 Part D drugs in 2027, 15 Part D and Part B drugs in 2028, and 20 Part D and Part B drugs in 2029.

According to 2 KFF tracking polls from fall 2023, there is overwhelming support among the general population for Medicare drug price negotiations, with 83% of those surveyed indicating that they are in favor of this initiative. However, there is a significant lack of awareness that these negotiations are taking place, as only 32% of those surveyed reported knowing about the negotiations. Bringing greater awareness to these efforts is important, especially given that the Congressional Billing Office released a final score of the Inflation Reduction Act, finding it would reduce deficits by $238 billion over a decade, including about $96 billion in savings from the federal government being able to negotiate for certain Medicare drugs.[30]

> "Half of all people on Medicare live on an income of $36,000 per person. When you see these numbers, you realize the trade-offs people are making. When they [patients] are facing huge out-of-pocket expenditures, it means they find something else to give up to purchase the drugs that they need."
>
> —TRICIA NEUMAN

Medicare Advantage Plans: Challenges and Trends

Over the past decade, there has been a notable increase in Medicare Advantage enrollment; more than half (54%) of Medicare Advantage-eligible people are now enrolled.[31] According to the Medicare Payment Advisory Commission, Medicare Advantage plans are paid for by the government via a per-member per-month payment for each person in a Medicare Advantage plan. This amount is adjusted based on health status. Some controversy exists regarding how this payment is calculated, since each plan is bidding against the traditional Medicare costs within a given area. These plans are then able to bid against the Medicare benchmarks, which are set at the county level, and use the difference for rebate dollars that can provide additional benefits to participants (**Figure 4**).

Two types of benefits are available: special supplemental benefits for the chronically ill and nonmedical benefits. The latter group includes caregiver support, food and produce, in-home support services, and nonmedical transportation. The increase in the number of Medicare Advantage plans offering these types of benefits could be a factor in the increased rates of enrollment.

However, Medicare Advantage insurers faced cost challenges in 2023, with their medical costs being higher than expected and a projected continuation of that trend. In response, CMS issued a final rule that revises the Medicare Advantage Program in 2025.[32] Major provisions of the 2025 final rule include:[32]
- New guardrails for plan compensation to agents and brokers to stop anticompetitive steering
- Limits to the distribution of personal beneficiary data by third-party marketing organizations
- Improving access to behavioral health care providers
- Mid-year enrollee notification of available supplemental benefits
- New standards for supplemental benefits for the chronically ill
- Enhancement of enrollees' rights to appeal a Medicare Advantage plan's decision to terminate coverage for nonhospital provider services

(*Continued on page 42.*)

Figure 4. Medicare Advantage Monthly Rebates and Percentage of Total Payment, 2018 to 2024

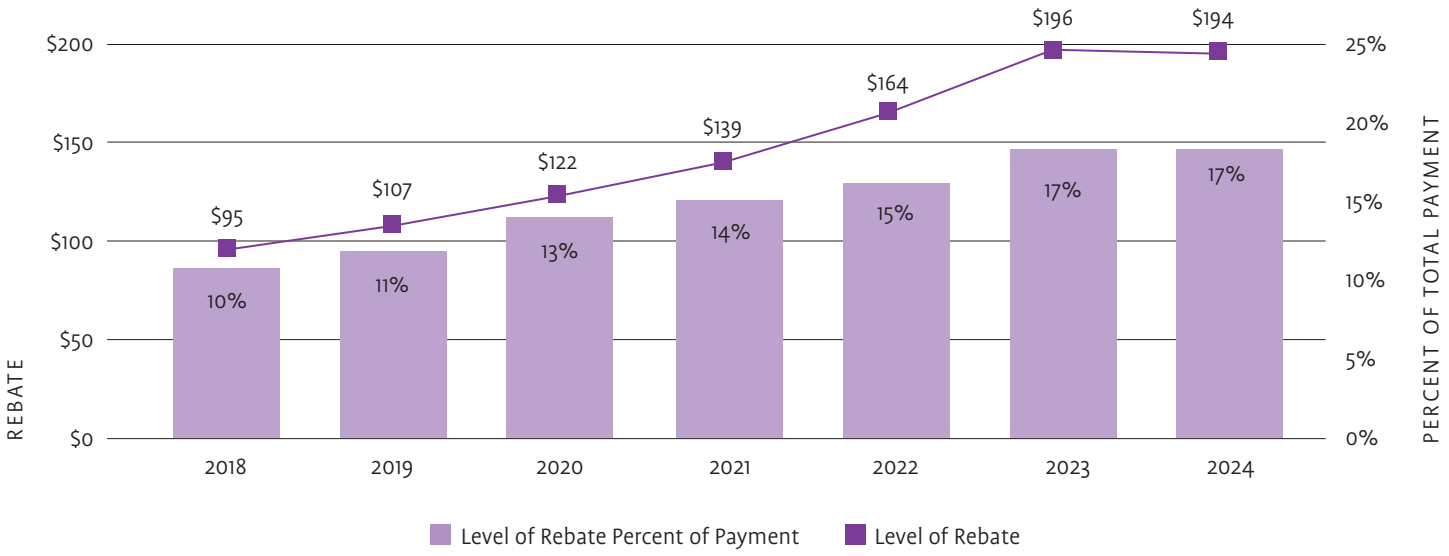
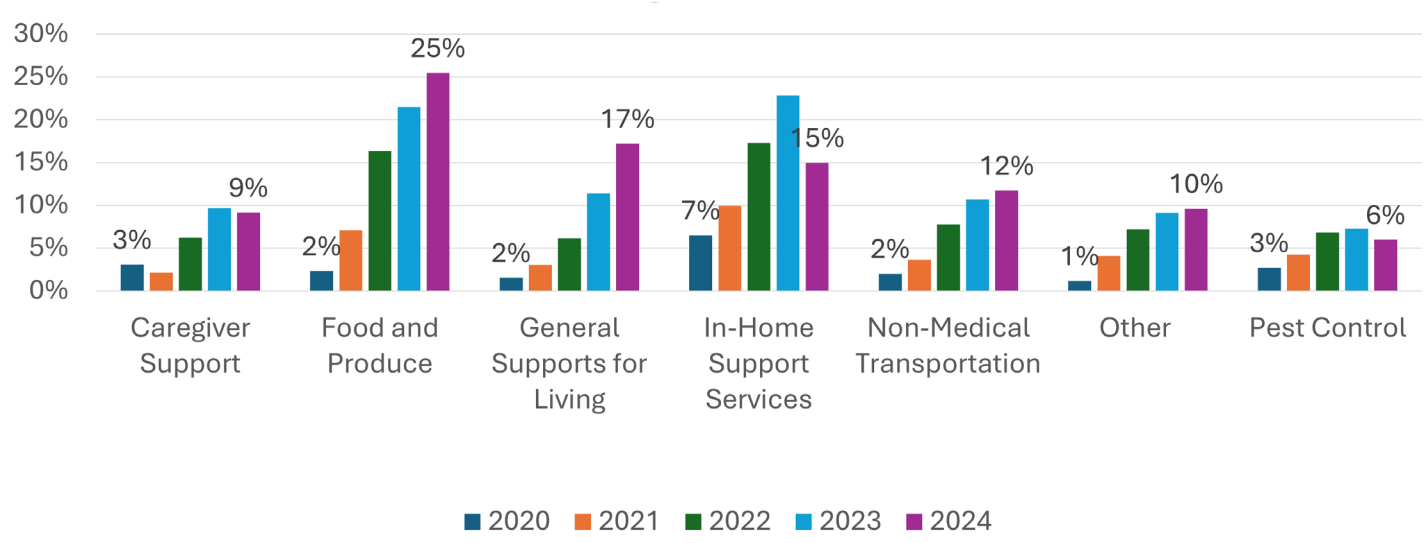


Figure 5. Percentage of Medicare Advantage Plans Offering Nonmedical Benefits, 2020 to 2024



"We need to have a better method of predicting drug shortages.... because on the pharmacy side, we wake up, we're informed that there's an immediate shortage and then suddenly we're having to ration therapy for patients."

– AMCCBS FACILITATOR

(*Continued from page 40.*)

- Annual health equity analysis of utilization management policies and procedures. Prior authorization policies and procedures may have a disproportionate impact on underserved populations and may delay or deny access to certain services. This rule ensures that Medicare Advantage organizations analyze their utilization management policies and procedures from a health equity perspective.

There has been congressional concern about prior authorizations, specifically about the fact that the reasons for denials are not generally collected by CMS, nor is the prior authorization data delineated by type of service. According to the 2024 Medicare Advantage and Part D Final Rule from CMS, the only true permissible use of prior authorization by Medicare Advantage plans is to confirm the presence of diagnoses or other medical criteria and/or to ensure that an item or service is medically necessary.[33] Under this rule, Medicare Advantage plans must follow local or national coverage determinations, as well as offer a minimum 90-day transition period if an enrollee under treatment switches to a new Medicare Advantage plan.[33]

An FAQ document was also released by CMS in February 2024, which stated that medical necessity must be based on the individual patient's circumstances.[34] Medicare Advantage plans can use artificial intelligence (AI) to assist in making coverage determinations, but AI must be consistent with posted internal coverage criteria; these criteria must also be made publicly available.[34]

In addition to these regulatory changes, Medicare Advantage plans are offering new types of benefits, including caregiver support, food and produce assistance, and nonmedical transportation (**Figure 5**).

Drug Supply Chain Challenges

As of April 4, 2024, the US Food and Drug Administration "still lists 16 commonly used oncology drugs as 'currently in shortage' or with limited availability," including carboplatin, capecitabine, cisplatin, methotrexate, and vinblastine.[35] During the worst of the drug shortage crisis, some providers had to prioritize patients being treated with curative intent over others.[35,36] "These shortages reflect broader challenges with prescription drug manufacturing integrity in the US, stemming from production delays, unavailability of raw ingredients, and/or quality deficiencies, among other factors."[37] At the time, providers and stakeholder groups like ACCC called for action to address the systemic issues that led to these and other drug shortages, including legislation to incentivize more domestic manufacturing of generic drugs.[38] One year later, AMCCBS attendees agreed that little has been done to legislatively fix these ongoing drug supply chain challenges.

"Traditionally, when you look in the United States, there are 2 main reasons why we see drug shortages," said Kirollos S. Hanna, director of pharmacy at Minnesota Oncology. "Number 1 is going to be a quality control issue from the manufacturer. And number 2, it might be a random act of nature or an act of God, like a storm or hurricane." Hanna went on say that current drug shortages are disproportionately affecting generic drugs, and that it was very rare to see shortages of newer—more costly—anticancer drugs. With margins so slim on generic drugs, pharmaceutical companies are not incentivized to manufacture these drugs. Hanna suggested that this issue should be addressed at the state and federal level and that the US needs to invest in manufacturing facilities to improve quality control and ensure adequate access to these commonly used drugs.

While the federal government has done little to alleviate the issues behind recent drug supply chain challenges, steps are being taken on the state level. "The state of Minnesota developed a coalition to work with the Minnesota Department of Health, and we've actually been able to get leaders from every health system within the state to start working through some of the challenges with drug shortages," said Hanna. This coalition found that drug shortages did not affect everyone equally. "Some health systems within Minnesota were completely unable to get any therapy—absolute zero allocation," shared Hanna. Whereas larger health care systems, like the University of Minnesota Mayo Clinic where Hanna practices, were still able to secure drug allocations, although it "had to limit utilization in certain indications to curative intent."

Ultimately, this statewide coalition fostered better transparency and clarity on the drug supply among the state's health systems and allowed providers to help each other during drug shortages. As Hanna said, "Sometimes it's a lot easier to transfer a drug than to transfer a patient." Accordingly, the coalition worked with the Minnesota Department of Health to develop protocols and policies to transfer medications from 1 institution to another for certain subsets of patients, for example, patients with curative intent who needed only 1 or 2 more cycles of chemotherapy.

It was no easy task for the Minnesota coalition to work through issues like chain of custody and policies for drugs supplied by a 340B institution. And what happens when a drug is transferred and not reimbursed by payers? Should the health care system then be charged for the drugs(s)? In the end, Hanna called for additional state and federal action to fix drug supply chain challenges. "It is a big issue that has a significant impact for patients...there needs to be a significant legislative corrective action in some shape or form around the quality of drug production."

RESEARCH AND CLINICAL TRIALS

A lack of diversity in clinical trials continues to be a pervasive issue in oncology research. As a result of such underrepresentation, research findings become less generalizable to the population at large, access to novel therapies are limited to certain groups, and underrepresented groups experience worse cancer outcomes. There is an increasing need for comprehensive visibility of available trials and patient eligibility to aid in recruitment, as well as skilled navigators to facilitate this process.

Facilitators:

- **Douglas Flora**, MD, LSSBB, executive medical director, Oncology Services, St. Elizabeth Healthcare
- **Praduman Jain**, CEO & founder, Vibrent Health; principal investigator, NIH All of Us Research Program
- **Aisha Montgomery**, MD, MPH, scientific director of research, Vibrent Health
- **Hala Borno**, MD, CEO & founder, Trial Library
- **Sylvia Zhang**, research partnerships lead, Trial Library
- **Bridget Gonzales**, CCRC, head of educational programs and customer success, Association of Clinical Research Professionals

Artificial Intelligence and Machine Learning Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD)

A program of the National Institutes of Health (NIH), this initiative seeks to use machine learning to identify and stratify nonclinical factors contributing to cancer disparity in rural Appalachia. The program has identified 4 hallmarks of success:

1. Develop a diverse, equitable, and inclusive artificial intelligence (AI) and machine learning workforce.
2. Increase knowledge, awareness, and national-scale community engagement and empowerment in AI and machine learning.
3. Use AI and machine learning to address disparities and minority health in behavioral health, cardiometabolic health, and cancer.
4. Build community capacity and infrastructure in AI and machine learning to address community-centric health disparities and minority health.

> "In what may be a theme today in this deep dive...I have all these great partners that I want to work with to improve clinical trial accrual, but first I have to convince legal, who are kind of the bottleneck in our health care system, and I suspect that's not unique."
>
> –DOUGLAS FLORA, MD

AIM-AHEAD focused its research of cancer disparities on rural Appalachia due to the staggering statistics of cancer deaths associated with that region. Thirty years ago, Appalachia had the lowest cancer mortality rates, but this trend has since reversed dramatically. While cancer death rates have decreased by 27% in the US overall,[39] they continue to rise in Appalachia, which now has a cancer mortality rate 32% higher than the overall US and 15% higher than the metropolitan counties surrounding rural Appalachia.[40] There are also high rates of cervical and colorectal cancers in this region, despite the ability to screen and prevent these forms of cancer.

Many social determinants of health exist for the population of rural Appalachia, including transportation issues, low health literacy, higher poverty rates, and higher uninsured rates, which may play a role in the cancer mortality disparity that has been observed in this area. Another unique social determinant of health experienced by these residents is a sense of fatalism, in that they feel doomed to get cancer and that there is nothing they can do to stop it.

The first phase of the AIM-AHEAD study was a pilot phase, designed to evaluate the levels of bias in the data shared by St. Elizabeth Healthcare in Kentucky to predict cancer survival. To do so, researchers took data from the NCI Surveillance Epidemiology and End Results (SEER) program, a national cancer registry, and compared it to the data that were extracted directly from the electronic health records (EHR) at St. Elizabeth. Researchers then combined clinical and social

"Insurance companies have identified loneliness as the number one predictor for hospitalization. Loneliness is higher than diabetes, hypertension, and medication noncompliance. It doesn't matter the comorbidity; loneliness is the highest linked driver to hospital admissions and readmissions. And what do many lonely people have in common: lack of a support structure."

– AMCCBS FACILITATOR

determinants of health factors to build a machine learning model to better predict colorectal cancer survival in rural Appalachia. The model predicted lower colorectal cancer survival for Appalachian patients, thus exhibiting bias, and was determined to be less accurate in predicting survival using the Appalachian EHR dataset.

Phase 2 of the study involved using EHR data to identify social determinants of health features that impact cancer survival, training the machine learning model with more EHR data from Appalachia to reduce bias, and stratifying social determinants of health features that affect model predictability for survival in rural Appalachian patients. The study population for phase 2 was adults who had been diagnosed with malignant colorectal or rectosigmoid cancer from 2000 to 2017. Several project partners from ACCC contributed data to the study, including St. Elizabeth Healthcare, Pikeville Medical Center, Thompson Cancer Survival Center, and the University of Pikeville.

The following social determinants of health, in order of most to least impactful, were observed: age, marital status, insurance, rural location, employment status, sex, race, and ethnicity. Regarding future research, the NCI plans to consult expanded EHR data from broader regions of the southeastern US affected by cancer by partnering with more cancer centers. Other plans include the following:

- Combine EHR data with commercially sourced and validated social determinants of health datasets.
- Build a machine learning model that can be used in community cancer centers to improve early diagnosis and treatment of cancer within rural, minority, and other underserved populations.
- Prioritize the collection of diverse, representative data and the use of AI and machine learning to address health disparities.

The NCI also recognizes the challenges for small cancer programs to participate in research due to issues of data sharing and are working to foster an infrastructure of sharing to contribute.

Community Oncology Registry

Cancer research cohorts do not reflect the diversity of individuals in the cancer community, as 85% of cancer trial participants are White males. This lack of diversity in cancer research cohorts leads to numerous disparities:

- Less generalizable research findings
- Development of less effective treatments
- Access to novel therapies being limited to certain groups
- Worsening cancer outcomes within underrepresented groups.

Vibrent Health partnered with ACCC to develop the Community Oncology Registry (CORe), which was designed to promote diversity and health equity in community cancer trials and to increase clinical trial diversity. The following goals were established for CORe:

- Develop a diverse approach to increase clinical trial diversity.
- Enhance generalizability of cancer research findings.
- Tailor cancer treatment approaches.
- Improve access to cutting-edge cancer treatments.
- Foster collaborative research.
- Increase participation of underrepresented populations.
- Understand health-related social factors that impact cancer risk and related outcomes.

Other important considerations during CORe's development include the substantive startup time involved in initiating clinical trials, ways to reduce protocol, and building a sustainable, durable research infrastructure that other community oncology programs can replicate. CORe also broadens the definition of who is included in the cancer community beyond patients with cancer. Cancer survivors, family members, care partners, and persons who feel they may be at increased risk of cancer for any reason were all invited to participate in a small feasibility study.

The 2 tiers of CORe are cancer trial matching and cancer research data resources. The first tier aims to increase access to clinical trial

"If we don't have Appalachian patients, if we don't have Asian Pacific patients, if we don't have African American patients, we will be spouting out the data that reflect people that look like me, and we might make deadly mistakes for the patients in our care."

– AMCCBS FACILITATOR

opportunities, increase awareness and education for participants, expand the participant pool for cancer research, and enhance the diversity of research cohorts. The second tier provides information about participant demographics, personal and family medical history, social determinants of health, EHR, and biospecimens.

CORe also implemented all regulatory compliances necessary for well-informed electronic consenting and for trials housed within the registry to be recognized by the FDA as valid. The end goal is to make clinical trial matching a much more expedited process by addressing recruitment, accrual, and retention issues. Building a common infrastructure of practices wherein eligible patients are listed would be instrumental in decreasing recruitment and startup time. Another goal of CORe is to enable widespread data sharing so that researchers can learn from one another through sharing de-identified patient data at the highest level of data security, privacy, and compliance.

To develop CORe, Vibrent partnered with the ACCC Community Oncology Research Institute (ACORI), St. Elizabeth Healthcare, Penn Medicine Lancaster General Health, and Wake Forest University. The following federal and commercial sponsors provided funding for CORe:

- Patient-Centered Outcomes Research Institute
- National Cancer Institute
- NIH National Center for Advancing Translational Sciences
- Advanced Research Projects Agency for Health.

Academic medical centers and NIH-designated comprehensive cancer centers have considerable resources and digital funding tools that community oncology practices typically do not. CORe works to bridge that gap and allow community oncology practices to benefit from investments being made at the national level.

One AMCCBS attendee said that it takes provider time to educate, consent, and enroll patients in clinical trials, and yet there's pushback to reimburse providers for this time as it is seen as "gaming the system and incentivizing physicians to enroll patients in trials. When really, NCCN guidelines are clear. For 15 years, enrollment in a clinical trial should be the standard of care if you have an appropriate trial at your cancer program." There was consensus that guideline adherence is a cornerstone of value-based care. But as one attendee questioned, "What then is the value of clinical trial enrollment? And why are payers not *valuing* providers by allowing them the time [and compensation] to be able to discuss clinical trials?"

Advancing Health Equity by Expanding Access to Cancer Precision Medicine

"Thank you for raising that issue," said Hala Borno, MD, CEO and founder of Trial Library, at the start of her presentation. "One of the core pieces of the Trial Library model is actually reimbursement—effort-based reimbursement for prescreening activities."

Trial Library is a UCSF (University of California San Francisco) public benefit company with a mission to advance access to cancer precision medicine, with a focus on oncology trial recruitment in partnership with community oncology settings. Trial Library is guided by a decade of evidence on the facilitation of clinical trial discovery and access. As part of its work, Trial Library identified the following pain points as barriers to oncology clinical trial recruitment:

- Staffing
- Limited bandwidth for prescreening patients
- Trial visibility
- Slot availability
- Incentivizing providers to discuss clinical trials
- Lack of funding for research.

Seventy-seven percent of patients that enroll in oncology trials do so because of a provider recommendation, so it is crucial to supply providers with the information they need to offer as many patients as possible with the chance to participate in a clinical trial. Trial Library therefore prioritizes partnership with community providers to expand clinical trial access to more patients.

A low rate of patient accrual to trial sites continues to be a problem and causes many therapeutic studies to fail early on. Low rates cause several other issues, including low accrual of diverse patients, overlooking eligible and potentially interested patients, and missing opportunities to expand the clinical trial portfolio. Low patient accrual can in part be attributed to competing priorities of providers, limited trial budgets and reallocation of resources, and a lack of clinical trial patient navigation services. Trial Library's model focuses on augmenting research capacity in the community by providing technology-enabled services, with the following goals in mind:

- Increase the number of patients referred to trials
- Improve the diversity of trial populations
- Boost operational efficiency
- Strengthen financial performance
- Expand the breadth of trials offered.

This model is funded by the study sponsor, enabling Trial Library to deploy services, technology, resources, and reimbursement in community settings. "And we are intentional about who was funding our innovation," shared Borno. "Because we believed that if the patient pays, we are not going to achieve health equity. If the provider pays, we are not going to achieve health equity. So, it really ought to be the study sponsor who funds this type of program."

> "At Trial Library, we use technology to facilitate discovery; we use reimbursements to unlock what we call the gatekeepers, which are providers."
>
> – AMCCBS FACILITATOR

Qualified prescreening staff (research coordinators) identify eligible patients for trials by running queries and conducting chart reviews within the cancer program's EHR. This step does not require extracting data or installing software to prescreen patients. Trial Library's trained research coordinators can do these tasks with view-only access. The result is a short, actionable, high-quality list of prequalified patients, rather than a long list of false positives generated by a computer alone.

Cancer programs are then reimbursed for integrating Trial Library into their workflow. Any personnel that receive the eligible patient report and notify a provider are reimbursed for engaging in these research activities and facilitating recruitment. Trial Library also applies technology-enabled navigation via a team of Ally Navigators that support clinical trial patients and provide resources for transportation, food, and lodging.

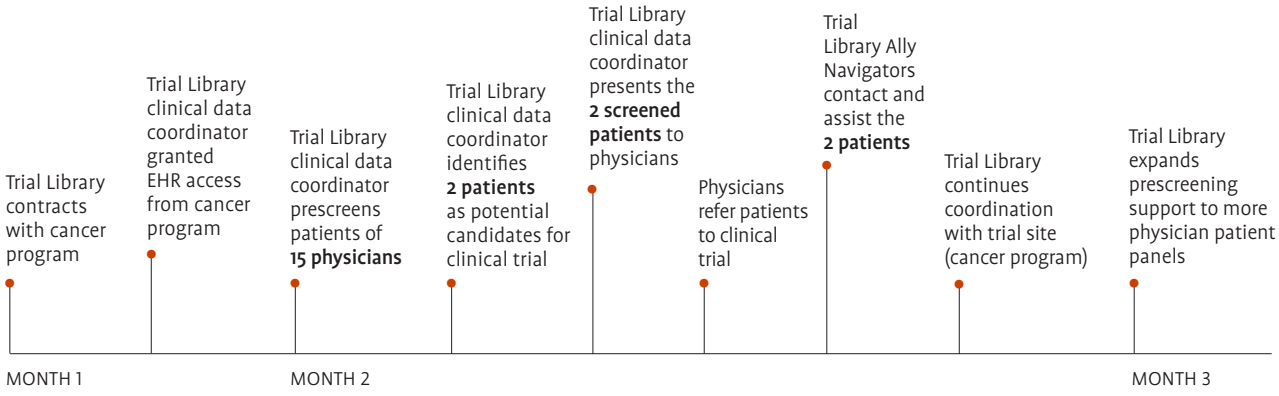
The Ally Navigation team serves as advocates for patients who are interested in and willing to participate in clinical trials and who are referred to Trial Library for a specific clinical trial opportunity. These navigators are diverse, multilingual, and available to be contacted through whatever means best suits patients' needs, whether it's phone, video chat, texting, or email. Navigators also have access to interpreting services to support all patients. Using a social determinants of health framework, Ally Navigators identify potential barriers patients may face when participating in their clinical trial and recommend free or low-cost resources to address those barriers on an individual level. Transportation, short-term lodging or hotel stays, and food security are all known barriers to clinical trial participation that Ally Navigators work to resolve.

These navigators are also responsible for referring patients to the clinical trial site through a highly qualified handoff to the clinical research site personnel. This handoff includes scheduling the first patient appointment, transferring that patient's medical records, and following up with the referring provider to give an update on the patient's care. The navigators' main goal is to ensure that patients who are interested and willing to participate in clinical trials have the means to do so and can get on and stay on their clinical trial.

> "Staffing is an issue. It has been really hard to find clinical research coordinators to do screening for clinical trials. They are a finite resource in our small part of the world because we're competing for hires with 2 giant CROs [contract research organizations] about 10 miles from our cancer center. We play this game where we raise salaries, and we hire and train 4 people, and then the CROs raise salaries, and they steal those same 4 people. It's a cycle."
>
> – AMCCBS ATTENDEE

Trial Library's services were specifically designed to address the burdens that community oncology programs face when participating in clinical trials at the provider, patient, and practice levels. Through partnerships with community providers across the US, Trial Library delivers accelerated and equitable recruitment to oncology clinical trials. To date, the organization has over 100 participating clinics and over 250 providers available to prescreen patients. **Figure 6** is

Figure 6. Trial Library Case Study: Ovarian Cancer Clinical Trial



"For providers, searching for a clinical trial is kind of like searching for a flight without knowing if there are seats on the plane. You're not going to sign up for that flight until you know that seats are available. So, slot availability is a real key pain point."

– AMCCBS ATTENDEE

a case study illustration of how Trial Library worked with a community cancer program to accrue patients with ovarian cancer to an active clinical trial.

Trial Library also partners with community-based programs and practices that do not have the resources or are simply not interested in opening up clinical trials but may refer to a trial site. "This effectively facilitates what we call decentralized prescreening," shared Borno. "Which is just broadening the denominator of patients that are being considered for a clinical trial."

During the robust Q&A after the Trial Library presentation, Borno told attendees that the model was designed to be provider-first, "meaning if we prescreen, the provider has to clinically agree and present the trial opportunity to the patient and ask the patient do they want to receive navigation support?" Only then can Trial Library's Ally Navigators contact the patient. "We never contact patients without those 2 pieces in place." Once patients consent to the study, Trial Library does a handoff to the research coordinator and the study personnel at the trial site to help follow the patient on the clinical trial. "One piece I would like to flag, however, is that if Trial Library identifies an ongoing social need, like a patient that is always going to need a car ride to the trial site, we make sure that there's a durable plan in place," Borno explained. "The last thing we want to do is get a patient to consent but then be unable to maintain the activities necessary to stay on the trial. So, we close the loop and make sure there's a durable pathway to keep the patient on the study."

Association of Clinical Research Professionals

The mission of the Association of Clinical Research Professionals (ACRP) is to promote excellence in clinical research and provide better resources, training, and awareness at clinical research sites. ACRP has 4 main certifications meant to build a strong base of foundational knowledge in clinical research, no matter one's initial background. ACRP also provides educational programs for training, professional development, and continued development in clinical research. In addition, the organization places an emphasis on connection through community. ACRP does so through an annual conference that allows opportunities for education and networking, as well as an online forum that runs throughout the year.

With funding from Genentech, ACCC is partnering with ACRP on an educational initiative to support community oncology programs. For this project, ACRP took its existing foundational instructor-led courses and added an additional layer of information specific to oncology clinical trials. The course itself is a blended learning environment, combining self-study and eLearning with opportunities to come together in an instructor-led training. During this instructor-led training, participants learn from patient case studies, stories, examples, and Q&A. Courses are offered in person and virtually, and are module based. ACRP identified the following next steps for this partnership program:

- Deliver the ACRP CRC Core Competency Foundations + Basics in Oncology Clinical Trials course to a select group of ACCC sites.
- Develop and deliver a Principal Investigator (PI) course that aligns with the ACRP Functional Competency Guidelines for PIs and Sub Investigators.
- Continue with site success measures to ensure sites can sustain and continue to conduct clinical trials. OI

Monique J. Marino is managing editor and Rachel Radwan is associate editor of Oncology Issues.

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