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SUBCUTANEOUS DRUGS ADVANCE. The under-the-skin delivery method is making strides with FDA approval of nivolumab and hyaluronidase-nvhy (Opdivo Qvantig) for treatment of solid tumors. In other news, the subcutaneous formulation of isatuximab (Sarclisa) reached coprimary end points in a phase 3 trial for multiple myeloma. The isatuximab trial used an on-body delivery system (Shown above) that allows freedom of movement and prevents patients from seeing the needle, [SP96](#), [SP98](#).

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Financial Navigation: Lessons From a Program in Practice

Natalie Dickson, MD, MMHC, FACP; and
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Introduction:
The Emergence of Financial Navigation
in Cancer Care

EVER SINCE CMS updated its physician fee schedule in 2024 and introduced new reimbursement codes for navigation—the Principal Illness Navigation codes¹—a lot of ink has been spilled by various media outlets expounding on the value of such navigation services in furthering health equity in cancer care.

Financial navigation² is a specific subtype of this broader concept, a system-level intervention that is both an acknowledgment and a response to the fact that the cost of cancer treatment can pose formidable challenges for patients and is a significant enough problem that it necessitates dedicated and trained personnel to address it. *Financial toxicity*—a term describing the distress and hardship caused by medical expenses—does not suffer

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THERAPEUTIC ADVANCES

Banner Year for Bispecifics as Therapies Advance Into the Community Setting

Ryan Flinn

PATIENTS WITH CERTAIN blood cancers such as multiple myeloma and leukemias often have to face a difficult choice: travel hundreds of miles to a major academic medical center for a month or more to receive a chimeric antigen receptor (CAR) T-cell therapy that could wipe out the disease, or stay local and receive a potentially less potent treatment.

For many patients, the distance, time away from home, and requirement for a caregiver companion are too burdensome.¹ However, advances with bispecific antibodies, a different type of engineered immunotherapy that binds to 2 different targets simultaneously, are changing the equation. Unlike CAR T therapies, bispecifics can often be delivered in outpatient settings, expanding access to care for patients who might otherwise have foregone treatment.² Because 85% of patients with cancer receive care in the community setting,³ clinicians have welcomed this advancement.

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FROM OUR PARTNERS

As COA President, Patt Promotes Advocacy: "Each of Us Holds an Important Part of the Story"

Interview by Mary Caffrey



Debra Patt, MD, PhD, MBA, FASCO, executive vice president at Texas Oncology and medical director for public policy within The US Oncology Network, became president of the Community Oncology Alliance on January 1, 2025.

TO SAY THAT Debra Patt, MD, PhD, MBA, FASCO, wears many hats would be an understatement. The longtime hematologist/oncologist, who practices in Austin, Texas, serves as executive vice president for Texas Oncology and medical director for public policy within The US Oncology Network. She is a professor at Dell Medical School at The University of Texas at Austin, where she received her bachelor's degree.

In 2023, Patt joined the board of directors for the American Society of Clinical Oncology, chairing the artificial intelligence (AI) task force, and was the first editor in chief of *JCO Clinical Cancer Informatics*. In January, after several years on the executive committee of the Community Oncology Alliance (COA), Patt became president of the organization that represents independent community oncology practices and physicians.^{1,2}

For years before becoming president, Patt testified before the US Congress on behalf of COA, making considerable headway on issues affecting community oncology. In everyday terms, she shared the harmful effects of vertical integration and resulting practices by pharmacy benefit managers (PBMs), sometimes

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Making Drug Delivery Easier for Patients

THIS ISSUE OF *Evidence-Based Oncology* is full of news about improving the way cancer drugs are administered to patients, whether that means trimming miles off their trip to the clinic or reducing the time spent in an infusion chair. The concept of time toxicity is relatively new to the literature, but it's been a reality for patients for decades.

As Ryan Flinn writes in the cover article on advances in bispecific antibodies, not every patient is a candidate for chimeric antigen receptor T-cell therapy, and even among those who are, not every patient has the resources to spend the time away from home to receive treatment in an academic center. The need for a caregiver may limit options, as well. Bispecifics can bring treatment closer to home, and partnerships with hospitals can make most of the process work in the community setting. As Flinn writes, the number of approvals for both new therapies and new indications for existing therapies in 2024 is highly encouraging. Beyond the increased options in multiple myeloma are emerging treatments for solid tumors and a breakthrough for a common pediatric leukemia, which was unveiled at the 66th American Society of Hematology Annual Meeting and Exposition in December.

This issue also covers advances in subcutaneous delivery. The under-the-skin method of administration is not new, but as Jackisch et al outlined more than a decade ago, the development of methods that would work with monoclonal antibodies proved challenging.¹ The development of recombinant hyaluronidase has been a game changer, as it previously allowed subcutaneous administration of the anti-CD38 inhibitor daratumumab (Darzalex Faspro). In late December, the FDA approved the PD-1 inhibitor nivolumab with hyaluronidase (Opdivo Qvantig) for use across multiple types of solid tumors.

And in early January came word that a phase 3 trial involving a rival anti-CD38 inhibitor, isatuximab, had met its copri- primary end points. That trial, IRAKLIA, involves using an on-body delivery system (see **Photo**), which allows the patient to move during drug administration, offering another quality-of-life upgrade.

All these changes promise to improve access and boost the likelihood that patients will stick with cancer treatment—the essential piece of better outcomes. ♦

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Mike Hennessy Jr
PRESIDENT & CEO

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Clinical Trials Must Represent Those Who Will Receive Therapy

ANDREW HERTLER, MD



HERTLER

IN THE NOVEMBER *Evidence-Based Oncology* article “As Myeloma Trials Tackle Frontline Treatment, Where Are the Black Patients?” the authors discussed results of the phase 3 IMROZ and PERSEUS trials that led to the recent FDA approval of isatuximab (Sarclisa) and daratumumab (Darzalex) in combination with the triplet of bortezomib (Velcade), lenalidomide (Revlimid) and dexamethasone for first-line multiple myeloma therapy. Although both trials represented significant advances in the treatment of multiple myeloma, they highlighted an ongoing problem with clinical trials: lack of diversity. Black patients made up only 0.9% of patients in IMROZ and 1.3% of patients in PERSEUS, even though 20% of patients with newly diagnosed myeloma are Black and 14% of individuals in the US are Black.

Underrepresentation of minority populations in clinical trials is not limited to just those with multiple myeloma. Results of a 2020 FDA Center for Drug Evaluation and Research study comprised of 32,000 patients in clinical trials revealed alarming gaps, as follows:

- Non-Hispanic Whites represented 75% of participants but only 59% of the US population.
- Hispanics are underrepresented 11% of participants, but 19% of the population.
- Blacks or African Americans are underrepresented at 8% of participants, but 14% of the population.

At Evolent, we develop clinical pathways that guide physicians to the best options for specific clinical scenarios. To determine these pathways, we look at the clinical trials leading to the FDA approval of the alternatives, comparing first efficacy, then toxicity, and as a last step, cost. When clinical trials are not representative of the patients who will be using the drugs, our task becomes more difficult. In addition to race, there is lower participation in clinical trials of patients of lower socioeconomic status as well as those who are older or who have more comorbidities. This can result from inaccessible trial locations and strict exclusion criteria.

Clinical trial populations are thus more likely to be younger, healthier, and less diverse than the general population. This may explain the disproportionate

results seen between clinical trial participants and real-world patients. Clinical trials measure the *efficacy* of a treatment under ideal conditions, whereas real-world data reflects the *effectiveness* of the treatment in everyday clinical practice. Real-world patients often have a wider range of health conditions and may not adhere to treatment protocols as strictly as trial participants. Study results have shown that real-world patients with certain cancers, such as multiple myeloma, often experience inferior progression-free survival compared with those in clinical trials. For example, real-world patients with multiple myeloma had 44% worse progression-free survival compared with clinical trial participants.

Evolent is taking several steps to address this issue. When making pathway decisions in conjunction with our scientific advisory board, we conduct a health equity assessment of every clinical trial by asking 2 questions: “Does the study include patients who are representative of the population in need?” and “Are there equal outcomes for all patient subgroups?” More weight is given to clinical trials whose participants adequately represent the populations we will be treating. Additionally, Evolent strongly encourages participation in clinical trials by rewarding providers for enrolling patients in them.

There are several other steps that can be taken more broadly by the health care industry. These include the following:

- Decentralized trials with more locations to increase access
- Use of artificial intelligence to match patients to clinical trial requirements
- Fewer exclusions with broader eligibility requirements
- Incentives for manufacturers to increase diversity in trials, such as expedited reviews, fee waivers, and extended exclusivity
- Use of community champions (nonbiased) and navigators to educate patients regarding clinical trials

Greater diversity in clinical trials will lead to a better understanding of how these drugs work and also allow us to get the best possible therapy to each patient. ♦

Andrew Hertler, MD, is senior adviser and chief medical officer emeritus for Evolent.

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TRUMP

President Donald J. Trump.



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Trump Reverses Some Biden Drug Pricing Initiatives, Potentially Impacting Medicare Costs

PEARL STEINZOR

PRESIDENT DONALD J. TRUMP'S second-term health care agenda is taking shape with a clear focus on undoing several Biden-era policies.¹ On Inauguration Day, January 20, 2025, Trump signed an executive order reversing initiatives aimed at reducing prescription drug costs for Medicare and Medicaid recipients, expanding the Affordable Care Act (ACA), and increasing protections for Medicaid enrollees. However, experts suggest that the changes may have little immediate impact on out-of-pocket (OOP) health care costs for most Americans.

For instance, one Biden-era initiative overturned by Trump had instructed Medicare to explore ways to reduce drug costs, including a potential \$2000 monthly OOP cap on certain generic medications. However, this proposal was still in the early stages of development, and its implementation was uncertain, according to Stacie Dusetzina, PhD, a professor in the Department of Health Policy at Vanderbilt University and board member of *The American Journal of Managed Care*, who spoke with NBC News.

Key initiatives by former US President Joseph R. Biden, such as the \$35 monthly cap on insulin, the \$2000 annual OOP cap on Part D prescription drugs for Medicare beneficiaries, and Medicare's authority to negotiate drug prices under the Inflation Reduction Act, remain unaffected by Trump's executive actions. However, these moves could hint that the incoming administration may be unwilling to move forward on any of these laid-out policies.

Key initiatives by former US President Joseph R. Biden, such as the \$35 monthly cap on insulin, the \$2000 annual OOP cap on Part D prescription drugs for Medicare beneficiaries, and Medicare's authority to negotiate drug prices under the Inflation Reduction Act, remain unaffected by Trump's executive actions. However, these moves could hint that the incoming administration may be unwilling to move forward on any of these laid-out policies.

What's Happening to the ACA?

Trump reversed Biden's executive order that extended enrollment periods for ACA plans in most states and provided additional funding to third-party organizations assisting with ACA sign-ups.² These measures had contributed to the Biden administration nearly doubling ACA enrollment to

approximately 24 million people, though much of the increase was driven by enhanced government subsidies that reduced ACA premium costs. The overturned policy allotted an enrollment period for an additional 12 weeks in 36 states, giving uninsured adults more time to sign up.¹

Trump Ends Drug Pricing Pilots

Trump revoked an executive order that had directed the Center for Medicare and Medicaid Innovation (CMMI) to develop 3 experimental drug pricing models, leaving their future uncertain.²

The first initiative aimed to assist state Medicaid programs in affording high-cost, highly effective cell and gene therapies by creating multistate purchasing agreements, allowing states to avoid payments for ineffective treatments. CMMI had already begun enrolling states in the program, with applications open until February 28, 2025.

The second model sought to reduce Medicare payments for drugs granted accelerated approval by the FDA, encouraging manufacturers to complete confirmatory trials promptly.

The third pilot project aimed to standardize \$2 flat co-pays for generic drugs used to treat chronic conditions in Medicare prescription drug plans, promoting medication adherence.

Abe Sutton, JD, a former White House and HHS aide, is expected to lead CMMI under the Trump administration.

Shifting Health Care Cost Priorities

Some of the policies Trump eliminated were previously aligned with his goals, suggesting a potential shift in his priorities, Larry Levitt, MPP, executive vice president of health policy at KFF, told NBC News.¹ By abandoning Biden's initiative to explore new ways to lower OOP costs for prescription drugs, Levitt suggests it may signal that Trump is less focused on addressing health care costs in the US.

It also remains unclear whether the Trump administration will support Medicare's ability to negotiate drug prices. On January 17, Medicare announced the next set of drugs up for negotiation, including semaglutide (Ozempic and Wegovy).

Arthur Caplan, PhD, head of the Division of Medical Ethics at NYU Grossman School of Medicine, told NBC News that Trump seems to be taking a cautious approach on health care costs, leaving Biden's larger initiatives largely untouched. Although Trump has advocated for a limited government role, Caplan said Trump is aware of the US's significantly higher health care costs compared with other countries and may recognize the need for government intervention. ♦

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Alcohol and Cancer Risk: Murthy's Parting Call for Warning Labels

MAGGIE L. SHAW



MURTHY
Vivek Murthy, MD, MBA,
was US Surgeon General,
2014-2017 and 2021-2015.

IN HIS FINAL WEEKS as US Surgeon General, Vivek Murthy, MD, MBA, sent out a call to action on January 3, 2025, for alcohol labels to now include cancer warnings, noting links to at least 7 cancer types.^{1,2}

With the US Dietary Guidelines for Americans set for a forthcoming update (the most recent guidelines cover 2020-2025³) and previous research also showing potential links between “habitual to light-moderate alcohol intake and lower rates of death, coronary artery disease, diabetes, congestive heart failure, and stroke,”⁴ there is renewed debate on both the benefits and risks of moderated drinking.¹ Action from Congress would be required to put labels on alcohol warning of cancer risk.

In 1987, the World Health Organization's International Agency for Research on Cancer first classified alcohol as a human carcinogen, citing the immediate metabolism of ethanol to acetaldehyde as a primary reason for it doing so.⁵ Per the CDC, this naturally occurring byproduct—which, when artificially manufactured, is used to produce industrial chemicals and as a solvent in the paper industry, among others⁶—can damage DNA via breaks and alterations and may have genotoxic properties, or the ability to induce change (mutation) within a cell's genetic material.⁷

A Call to Action

In his call to action, Murthy referred to research showing correlations between even the recommended guidelines of alcohol intake and the aforementioned 7 cancer types, which are oral cavity, pharynx, larynx, esophagus, colorectum, liver, and breast.^{1,5} His report also differentiates between absolute and relative risk, explaining that these differ within men and women and between the sexes, as well.¹ For example, at less than 1 drink per week, the absolute risk of breast cancer for a woman is approximately 11.3%, whereas for men, it's close to 10% for an alcohol-related cancer. For 2 drinks per day, the risks jump to 15.3% and 13%, respectively. Overall, alcohol is the third-leading cause of preventable death, behind tobacco and obesity.¹

“Alcohol is a well-established, preventable cause of cancer responsible for about 100,000 cases of cancer and 20,000 cancer deaths annually in the United States—greater than the 13,500 alcohol-associated traffic crash fatalities per year in the US—yet the majority of Americans are unaware of this risk,” Murthy said in a statement.² “This advisory lays out steps we can all take to increase awareness of alcohol's cancer risk and minimize harm.”

However, the new presidential administration that took office January 20 has the potential to include health leadership under surgeon general nominee Janette Nesheiwat, MD, and HHS secretary nominee Robert F. Kennedy Jr, Whether Murthy's recommendation comes to pass is anybody's guess.⁸

What Will Dietary Guidelines Say?

What is known is that 2025 will bring an update to the nation's dietary guidelines, which will incorporate research from 2 scientific reviews on alcohol consumption. As the current guidelines were being drawn up, the authors consulted evidence showing alcohol to be a carcinogen but ultimately

omitted a potential recommendation to cap the daily limit at 1 standard drink for men—meaning the daily limit of 2 drinks remained.¹ However, the definition of a standard drink varies depending on the amount of alcohol consumed, per the National Institute on Alcohol Abuse and Alcoholism. For example, 1 standard drink of wine (5 fl oz) contains approximately 12% alcohol; brandy or cognac (1.5 fl oz), 40% alcohol; and fortified wine (3-4 fl oz), 17% alcohol.⁹

Globally, just 47 countries have warning labels for alcohol, but only South Korea includes a specific warning of liver cancer.¹ In 2026, Ireland will begin using labels on beer, wine, and liquor that warn of direct correlations between alcohol and fatal cancers.¹⁰

The current warning label for alcohol in the US only advises against pregnant women drinking and that alcohol impairs the ability to safely operate machinery or drive a car.¹¹ It has remained unchanged since 1988.¹ Murthy's push also comes amid staunch pushback from the alcohol industry, which has historically rallied against labels that mention any link with cancer. ♦

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SPOTLIGHT

“This Is Important Information to Get Out”

Produced by Mary Caffrey

DEBRA PATT, MD, PhD, MBA, is a medical oncologist/hematologist and breast cancer specialist who practices in Austin, Texas, for Texas Oncology. She is the current president of the Community Oncology Alliance, a member of the board of directors for the American Society of Clinical Oncology, and medical director for public policy for The US Oncology Network. As part of a wide-ranging interview (See **Cover**), *Evidence-Based Oncology (EBO)* asked Patt about the US surgeon general’s January 3, 2025, advisory on alcohol and cancer risk.



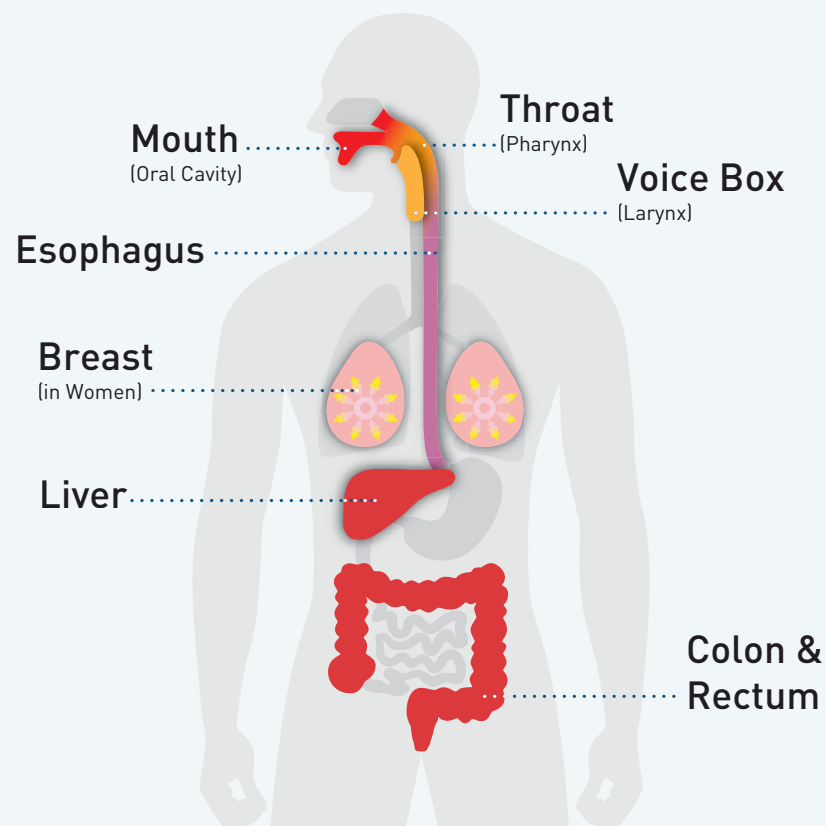
PATT

EBO: What were your thoughts on the surgeon general’s advisory?

PATT: I saw the surgeon general’s report on alcohol and cancer, and that increased alcohol intake is associated with some particular cancers, specifically, head and neck cancer, esophageal cancer, breast cancer, liver cancer, and colorectal cancer.

Alcohol intake is associated with an increased risk of those cancers; in particular, heavy alcohol intake is associated with an increased risk of those cancers. This is important information to get out. We need to be talking to our patients about it and allow them to make educated decisions about how they might modify their lifestyle in order to continue to live cancer free. ♦

Consuming alcohol increases the risk of developing at least 7 types of cancer



Source: Adapted from Office of the US Surgeon General / HHS. “Alcohol and Cancer Risk.” National Cancer Institute, <https://www.cancer.gov/aboutcancer/causes-prevention/risk/alcohol/alcohol-fact-sheet>

SPOTLIGHT

Rikki Cannioto, PhD, EdD, MS: “There Is a Gap in Public Health Awareness”

Produced by Mary Caffrey

WHAT DOES A CANCER epidemiologist have to say about the recent US surgeon general’s report about alcohol and cancer risk? Rikki Cannioto, PhD, EdD, MS, is an assistant professor of oncology in the Department of Cancer Prevention and Control at Roswell Park Comprehensive Cancer Center in Buffalo, New York. Cannioto is also a specialist in ovarian cancer epidemiology and focuses on the mechanisms of physical inactivity, obesity, and lifestyle that affect cancer risk. She answered questions from *Evidence-Based Oncology (EBO)* about the report and the call for warning labels on alcohol.

EBO: What were the most important takeaways from the surgeon general’s report on alcohol and cancer risk?

CANNIOTO: Alcohol consumption is the third leading preventable cause of cancer risk, following smoking and obesity. [Although] most Americans understand that excess body weight and smoking are associated with increased cancer risk, there is a gap in public health awareness about the causal link between alcohol and cancer risk, which has persisted for decades. However, there is now sufficient scientific evidence to show a causal link between alcohol consumption and

increased risk of developing at least 7 cancers, including cancer of the breast [in women], colorectum, esophagus, liver, mouth [oral cavity], throat [pharynx], and voice box [larynx].

EBO: Research on the links between alcohol and risk in certain cancers has been ongoing for many years. Why do you think it has taken so long for a report of this high profile to be released?

CANNIOTO: Although a link between alcohol and cancer risk began to emerge in the 1980s, numerous high-quality publications in recent decades have solidified our understanding of the causal biological pathways underlying the associations of alcohol consumption with increased risk of developing at least 7 cancer types.

EBO: Do you think having a report from the surgeon general will help open the doors to communication between doctors and patients about alcohol risks?

CANNIOTO: There is a growing body of scientific evidence showing that a constellation of healthy lifestyles, including being physically active,

maintaining a healthy body weight, eating a healthy diet, limiting alcohol, and avoiding smoking, are conducive to cancer prevention. [Although] clinical care teams routinely counsel patients about the well-established risks of smoking and obesity, the new surgeon general's advisory will better position clinicians to inform patients about the established associations [between] alcohol consumption and increased cancer risk, which will heighten public awareness. Importantly, publication of this report may be

leveraged to incorporate alcohol screening and referral for intervention or treatment as needed. ♦

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What Recent Evidence Is Telling Us About Alcohol and Cancer

PRODUCED BY MARY CAFFREY



LOCONTE

Noelle LoConte, MD, hematologist and medical oncologist and associate professor, University of Wisconsin-Madison.

THE US SURGEON GENERAL'S REPORT calling for warning labels linking alcohol with cancer risk may have generated headlines, but for researchers who study these mechanisms, this was hardly news (See **Related Article**). In December 2020, as alcohol use was rising around the globe during the COVID-19 pandemic, the National Cancer Institute (NCI) convened a workshop and public webinar of experts to evaluate existing evidence and identify gaps in what was known about the connections between alcohol and cancer.¹ The group also discussed what can be done to better communicate alcohol's mortality risks.

One of those experts was Noelle LoConte, MD, a hematologist and medical oncologist at the University of Wisconsin-Madison and lead author of a 2018 statement on alcohol and cancer for the American Society of Clinical Oncology.² In 2023, LoConte was the senior author of a survey of Wisconsin patients with cancer, which found that increased alcohol consumption during the pandemic was associated with financial hardship and declining mental health.³

Given that evidence about alcohol and cancer has been accumulating for decades, *Evidence-Based Oncology* (EBO) asked LoConte: What has changed? Here are LoConte's answers to questions from EBO, edited lightly for clarity:

EBO: What are the most important things we have learned about the mechanisms of how alcohol drives cancer risk? Is there new evidence that has come to light that moved us past a "tipping point" and toward a stronger public education effort?

LOCONTE: There is some newer evidence that, in my mind, has proven the "abstainer bias" as the cause of the J-shaped curve that, for some time, seemed to favor that 1 drink a day is healthier than not drinking [or drinking more]. The 2023 study⁴ I am referring to was able to control for people [who] abstained but previously drank vs those who never drank. The abstainers group likely drank enough for that to impact their current health. The never-drinkers, indeed, were the healthiest group.

EBO: We have heard more about increased alcohol use among women. What are the particular issues with how alcohol drives cancer risk in the body that are of special concern to women?

LOCONTE: The major concern here is breast cancer. Alcohol raises estrogen, which in turn raises the risk of breast cancer. The other issue is that alcohol use among women was shown to increase greatly during and after the pandemic,^{5,6} which, based on other stressful events that led to communities increasing their alcohol consumption, [such as] 9/11 or Hurricane Katrina, will likely be sustained use.

EBO: The 2020 NCI workshop¹ addressed the challenges of communication on alcohol and cancer risk. What do you see as the chief barriers to building public awareness and acceptance that this risk merits action?

LOCONTE: It's a nuanced message—it's some cancers, not all cancers. Some moderate or intermittent use likely is OK. The way alcohol causes cancer is variable, depending on the cancer, etc. That makes pithy or quick messaging hard. The other barrier is that a lot of doctors drink. For example, we know that doctors who are obese are less likely to speak to their patients about obesity, and back in the day, doctors who smoked were less likely to address tobacco use with their patients. Lastly, the alcohol industry is a powerful industry that is opposed to this messaging about alcohol as a carcinogen. ♦

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NCCN Publishes Patient Guidance on Genetic Testing for Cancer Risk

ROSE MCNULTY

THE NATIONAL COMPREHENSIVE CANCER NETWORK (NCCN) published a new resource with evidence-based information about current recommendations for hereditary and familial cancer risk. These guidelines aim to inform patients about the assessment and testing for inherited genetic mutations that can increase cancer risk.¹

“No other landscape in medicine has changed as drastically as the field of clinical genetics,” Mary B. Daly, MD, PhD, FACP, director, Risk Assessment, Fox Chase Cancer Center and chair, NCCN guidelines panel for genetic/familial high-risk assessment: breast, ovarian, pancreatic, and prostate cancer, said in a statement. “The changes have been facilitated by the work of the Human Genome Project but have gone way beyond its scope.”

The Human Genome Project was an international effort that produced the first human genome sequence in 2003.² The sequence accounted for more than 90% of the human genome, which was as close to complete as was possible with DNA sequencing at the time.

“Advances in technology have been a major driver of the explosion of knowledge in genetics, now allowing us to sequence the entire human genome in a short period of time and at a fraction of the cost of previous years,” Daly said.¹ “This has led to a better understanding of the natural history of cancer, the ability to assess genetic risk for cancer across

populations, the development of clinical management strategies to reduce cancer risk, the development of novel therapeutic agents [that] target genetic alterations, and to improved education of patients and providers about genetic risk.”

Genetic testing assesses patients for specific inherited mutations that may raise their cancer risk. Approximately 5% to 10% of cancers are thought to be caused by such mutations. Tests are typically requested by providers, including doctors and genetic counselors, who determine whether an individual’s medical history and family medical history indicate a possibility of inherited cancer.

Genetic testing assesses patients for specific inherited mutations that may raise their cancer risk. Approximately 5%



DALY

Mary B. Daly, MD, PhD, FACP, director, Risk Assessment Program, Fox Chase Cancer Center.



HEMPEL

Heather Hempel, MS, CGC, associate director, Division of Clinical Cancer Genomics, City of Hope.

THERAPEUTIC ADVANCES

FDA Approves Datopotamab Deruxtecan for HR-Positive/HER2-Negative Metastatic Breast Cancer

Pearl Steinzor

THE FDA APPROVED datopotamab deruxtecan-dlnk (Datroway; Daiichi Sankyo) on January 17, 2025, for adult patients with unresectable or metastatic hormone receptor-positive/HER2-negative breast cancer who have previously received endocrine-based therapy and chemotherapy.¹

The approval is based on findings in TROPION-Breast01 (NCT05104866), a multicenter, open-label, randomized trial that showed significant improvement in progression-free survival (PFS) with datopotamab deruxtecan-dlnk compared with chemotherapy (6.9 vs 4.9 months; HR, 0.63; $P < .0001$). Although overall survival (OS) was similar between groups, the confirmed objective response rate (ORR) favored datopotamab deruxtecan-dlnk (36% vs 23%).

Datopotamab deruxtecan-dlnk is a Trop-2-directed antibody-drug conjugate that showed a statistically signifi-

cant and clinically meaningful improvement in PFS compared with chemotherapy among patients with previously treated hormone receptor-positive/HER2-negative inoperable or metastatic breast cancer.² Findings from the phase 3 TROPION Breast-01 trial were presented during the 2023 San Antonio Breast Cancer Symposium. The study was designed to evaluate the efficacy and safety of datopotamab deruxtecan-dlnk in patients with unresectable or metastatic hormone receptor-positive/HER2-negative breast cancer.¹

Eligible patients had experienced disease progression, were unsuitable for further endocrine therapy, and had received 1 to 2 prior lines of chemotherapy for metastatic disease. Key exclusion criteria included a history of

continued ▶

to 10% of cancers are thought to be caused by such mutations.³ Tests are typically requested by providers, including doctors and genetic counselors, who determine whether an individual's medical history and family medical history indicate a possibility of inherited cancer.

“It's very important for everyone to understand that their cancer risks based on their personal or family history, [as] their personal risk level may necessitate earlier, more frequent, and/or more intensive cancer surveillance.”

—Heather Hampel, MS, CGC,
associate director, Division of Clinical Cancer Genomics,
Department of Medical Oncology and Therapeutics Research,
City of Hope

The new guideline is the NCCN's first patient resource on the topic of cancer genetics and hereditary cancer risk. It is a free resource that presents evidence-based information in a plainspoken way, adding to a library of

more than 70 free books with information on cancer prevention, screening, diagnosis, treatment, and supportive care offered by the NCCN.¹

“It's very important for everyone to understand their cancer risks based on their personal or family history, [as] their personal risk level may necessitate earlier, more frequent, and/or more intensive cancer surveillance,” said Heather Hampel, MS, CGC, associate director of the Division of Clinical Cancer Genomics in the Department of Medical Oncology and Therapeutics Research at City of Hope.¹ “This is the best way to ensure that you are doing everything you can to prevent cancer or catch it early when treatment has the best outcome. You can find a local cancer genetic counselor at findageneticcounselor.org if you would like a personalized cancer risk assessment. This often includes genetic testing to determine [whether] you have a hereditary cancer susceptibility running in your family.” ♦

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THERAPEUTIC ADVANCES

CONTINUED FROM PREVIOUS PAGE

or ongoing interstitial lung disease/pneumonitis, clinically active brain metastases, significant corneal disease, or an ECOG performance status greater than 1.

The median progression-free survival in the datopotamab deruxtecan arm was 6.9 months, compared with 4.9 months in the chemotherapy arm. Although median overall survival was similar between the 2 groups, the confirmed objective response rate was higher in the datopotamab deruxtecan arm (36% vs 23%), and duration of response was longer in this arm (6.7 months vs 5.7 months) compared with chemotherapy.

A total of 732 patients were randomly assigned 1:1 to receive either datopotamab deruxtecan-dlnk or the investigator's choice of chemotherapy (eribulin, capecitabine, vinorelbine, or gemcitabine). Randomization was stratified by prior chemotherapy lines, CDK4/6 inhibitor treatment, and geographic region.

The median PFS was 6.9 months (95% CI, 5.7-7.4) in the datopotamab deruxtecan-dlnk arm compared with 4.9 months (95% CI, 4.2-5.5) in the chemotherapy arm (HR, 0.63; 95% CI, 0.52-0.76; $P < .0001$). Although median OS was similar between the 2 groups (18.6 months with datopotamab deruxtecan-dlnk vs 18.3 months with chemotherapy [HR, 1.01; 95% CI, 0.83-1.22]), the confirmed ORR was higher in the datopotamab deruxtecan-dlnk arm at 36% (95% CI, 31-42) compared with 23% (95% CI, 19-28) with chemotherapy. The median duration of response was also longer with datopotamab deruxtecan-dlnk at 6.7 months (95% CI, 5.6- 9.8) vs 5.7 months (95% CI, 4.9-6.8) in the chemotherapy arm.

Datopotamab deruxtecan-dlnk was associated with several common adverse events (AEs), which occurred in 20% or more of patients. These included stomatitis, nausea, fatigue, and alopecia, along with laboratory abnormalities such as decreased leukocytes, lymphocytes, neutrophils, hemoglobin, and calcium levels. Other frequently reported AEs were constipation, dry eye, and vomiting. Elevated levels of liver enzymes, including alanine transaminase, aspartate transaminase, and alkaline phosphatase, were also observed, as well as keratitis. These findings highlight the need for monitoring and managing potential toxicities associated with the treatment.

The recommended dose of datopotamab deruxtecan-dlnk is 6 mg/kg administered intravenously every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity occurs. ♦

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Song Park, MD, on Equitable Access Intertwined With User-Friendly Tech

KYLE MUNZ

AT A RECENT Institute for Value-Based Medicine event in Seattle, Washington, Song Park, MD, assistant professor, Department of Dermatology, University of Washington Medicine, offered the dermatologist's perspective during a panel discussion titled "Best Practices in Skin Cancer Treatment: Navigating the Patient Journey." Experts discussed the intricacies of patient journeys following a skin cancer diagnosis, as well as current best practices in the field. Here, Park provides *Evidence-Based Oncology (EBO)* with insights into how clinicians can be the best support system for their patients and the influence of value-based care on the accessibility of treatments.

This transcript has been lightly edited.

EBO: In value-based care models, how can health care providers best provide emotional and psychological support for patients with skin cancer while optimizing outcomes and resource allocation?

PARK: I believe that it is most important to provide very clear and concise information when they get the diagnosis: What's the prognosis, what [are] the treatment options, and what really is expected for the patients? Make it clear that we are available to answer any questions, and then provide the right resources and be there for them. As a doctor or provider, that's the best thing we could do for a patient. And as an institute, we have a lot of support systems [such as] social workers or nursing support to help.

EBO: What role does value-based care play in addressing barriers to accessing timely and effective skin cancer treatment, and how can it help reduce disparities in care delivery?

"As a dermatologist, there are 2 parts that we can really help with: Getting the diagnosis early enough when someone finds suspicious lesions, and then getting into the right treatment or right treatment team when they get the diagnosis."

—Song Park, MD,
assistant professor, Department of Dermatology,
University of Washington Medicine

PARK: Good question. As a dermatologist, there are 2 parts that we can really help with: Getting the diagnosis early enough when someone finds suspicious lesions, and then getting into the right treatment or right treatment team when they get the diagnosis.

[For] the first part...[streamline] those referral pathways and actively [use] teledermatology—in some institutes, it's called e-consult, [which uses] high-resolution photos to be reviewed by a dermatologist or specialist so they can best try and see [whether] it is concerning, [whether the] patient needs to be seen on [the] earlier side, or [whether] this is something that we cannot watch. If one has that system...in their practice model, that really helps people with some concerning skin lesions...to get the diagnosis early or be reassured.

The second part, once one gets the diagnosis, especially if it is aggressive or a more severe diagnosis or stage, getting them connected with the multidisciplinary team with the right specialties really helps with moving that care fast enough and getting the right amount of care.

EBO: Are there any challenges to ensuring these innovations remain accessible for different patient populations?

PARK: In the general population, particularly for rare cancers or those areas that are evolving fast, it's hard [for anyone] to stay updated. So, increasing the awareness of what's new [in technology] and how others are using and sharing that as a professional society would help. As for patient barriers...these days, apart from access, there [are] also technology considerations. It's not like rocket science technology, but our [older] patients are less familiar with using those [information technology] devices, computers, or even taking a photo of their lesion and uploading. They sometimes need help from other people, so making those easier to access and easier to use may help with patient care. ♦



PARK

Song Park, MD, assistant professor, Department of Dermatology, University of Washington Medicine.

SPOTLIGHT

Leveraging AI and Community Health Workers to Boost Trial Access

Interview by Maggie L. Shaw



BOND

KASEY BOND, MPH,
executive director, administration,
Perlmutter Cancer Center, NYU
Langone Health.

VAT A RECENT GATHERING of the Institute for Value-Based Medicine presented by NYU Langone Health and *The American Journal of Managed Care (AJMC)*, the evening's theme was "Enhancing Community Cancer Programs With Academic Excellence Through Strategic Partnerships." Panelist Kasey Bond, MPH, executive director of administration at Perlmutter Cancer Center in New York, New York, discussed how the contributions of community health workers increase clinical trial access and how technology can help to facilitate the process. Bond oversees Perlmutter's strategic planning and the operations across the NYU Langone Health network, which includes Manhattan, Brooklyn, Queens, and Long Island.

This transcript has been lightly edited.

AJMC: How can technology and community health workers be leveraged through collaboration to expand clinical trial access?

BOND: It fits into 2 parts for me. One, the community health workers in general are an extremely important part [of] expanding access [to] clinical trials. Clinical trials in certain communities have a certain stigma associated with them, and some patients are extremely nervous about participating or might not even know to ask about a clinical trial as an option. Educating our community health workers to explain to patients what a clinical trial means [and] how it might benefit them is so valuable.

Often, the clinical trial is the best possible available treatment course for this patient, and we want to make sure that they have a space to ask questions without the fear of somebody judging them. We work in the industry, and sometimes you feel embarrassed to ask a question in front of a physician. You don't want them to think you don't know what you're talking about. So, the community health worker is an extremely valuable resource in making patients feel comfortable to ask about their treatment options.

When you couple that incredible workforce with technology—AI [artificial intelligence] screening is a great example that we talked about at the event—that can help us to be able to identify patients in advance who might be appropriate for a particular trial. That screening process is

extremely cumbersome when done manually, and AI seems like a promising solution to be able to identify patients earlier and easier.

Then when we can connect our community health workers with those patients who are likely eligible, it brings together a higher success rate in identifying patients who are appropriate for trials and could really benefit from them.

It's important for people to hear it from a member of their own community. It's easy to believe that a physician, nurse, or anybody at a hospital or practice might have a vested interest in why they want you to participate in a study, so I think the community health worker, in this way, really serves as a trusted third party. There's no vested interest for them; their only intention is to provide the patient with the most meaningful and useful information for their specific case.

I also think there's fear in a lot of communities about the fact that there is so little minority representation in many clinical trial accruals that...there's some concern that those trials weren't conducted in populations that look like theirs. This is the highlight of why it's so important for us to offer clinical trials in a wide variety of communities, but it also is contributing to that distrust that we were talking about, [and] rightfully so.

Having somebody who understands the nuance [and concerns] of that culture...is a beneficial way to make patients feel more educated and empowered to make their own decisions. ♦

The 10 Americas: Persistent and Widening Life Expectancy Disparities in the US

GIULIANA GROSSI

LIFE EXPECTANCY GAPS in the United States have widened dramatically over the past 2 decades, causing disparities across racial, ethnic, and geographic lines to reach a staggering 20.4 years by 2021, according to a study published in *The Lancet*.¹ The research, an expansion of the landmark Eight Americas study, reveals how structural inequities and the COVID-19 pandemic have deepened health divides, leaving some groups—particularly American Indian and Alaska Native populations in the West—facing steep declines in longevity.

The mortality disparities observed in the previous research found that among the 8 Americas, each containing millions of individuals were significantly pronounced when compared internationally. The authors noted that these variations in life expectancy cannot be fully explained by race, income, or access to basic health care alone.²

By analyzing data from 2000 to 2021 in the new study, researchers identified 10 distinct “Americas” based on race, ethnicity, geography, income, and segregation levels, revealing a widening gap in life expectancy among these groups.¹

“Revisiting the Eight Americas study 2 decades later has provided important insights into where progress has (or has not) occurred, and how an inter-related set of contextual factors have contributed to the USA failing so many Americans and falling behind so many of its peer nations,” the researchers wrote. “At the beginning of the 21st century, there was already a 12.6-year gap in life expectancy among Americas, but this gap grew even larger during the 2000s and 2010s and accelerated to 20.4 years after the first 2 years of the COVID-19 pandemic.”

Life Expectancy Trends Across 10 Americas

The study categorized the US population into 10 mutually exclusive groups, refining the original 8 Americas by adding 2 additional groups representing the Latino population.

The 10 Americas defined:

- **AMERICA 1:** Asian individuals
- **AMERICA 2:** Latino individuals in other counties
- **AMERICA 3:** White (majority), Asian, and American Indian or Alaska Native (AIAN) individuals in other counties
- **AMERICA 4:** White individuals in non-metropolitan and low-income Northlands
- **AMERICA 5:** Latino individuals in the Southwest
- **AMERICA 6:** Black individuals in other counties
- **AMERICA 7:** Black individuals in highly segregated metropolitan areas
- **AMERICA 8:** White individuals in low-income Appalachia and the Lower Mississippi Valley
- **AMERICA 9:** Black individuals in non-metropolitan, low-income Southern areas
- **AMERICA 10:** AIAN individuals in the West

In 2000, life expectancy ranged from 70.5 years for America 9 to 83.1 years for America 1, a gap of 12.6 years. By 2021, the gap had widened to 20.4 years, with America 9 at 65.2 years and America 1 at 85.6 years. Data showed that disparities grew particularly sharply during the first 2 years of the pandemic.

Growing Disparities in Life Expectancy

From 2000 to 2019, most Americas experienced improved life expectancy, with notable gains for Black populations (Americas 6, 7, and 9). However, America

10, comprising AIAN individuals in the West, experienced consistent declines even before the pandemic. During the COVID-19 pandemic, life expectancy dropped significantly across most groups, but the decline was especially pronounced for America 10, exacerbating pre-existing disparities.

Key shifts in life expectancy and socioeconomic factors have been notable in the Americas over the years. By 2010, America 6 surpassed America 8 in life expectancy, attributed to significant improvements in the former while the latter experienced stagnation. From 2000 to 2019, America 5 saw faster increases in life expectancy, although this trend dramatically reversed in 2020. Meanwhile, America 3 consistently ranked highest in income and educational attainment, yet it fell short in life expectancy compared to America 1.

Drivers of Disparity: The Role of Geography, Race, and Income

The study highlights the complex interplay of geographic, racial, and economic factors in shaping health outcomes. While income and education levels influenced disparities, they did not entirely account for the differences, underscoring the importance of structural and systemic inequities.

The COVID-19 pandemic magnified these vulnerabilities, with socially and economically disadvantaged groups experiencing disproportionate impacts on health and mortality. According to the study, the results emphasize the need for targeted, data-driven policies to address health inequities.

Implications for Policy and Action

“Life expectancy declined in all ten Americas in 2020, and rebounded partly in only three Americas in 2021, with the Americas that were worst off before

the pandemic seeing some of the largest overall losses from 2019 to 2021,” the authors wrote. “These persistent inequities among ten different Americas warrant urgent attention. We hope these estimates inspire action and serve as one tool (among many) for guiding the development of interventions to reduce and ultimately eliminate these inequities by focusing on the health of the most [marginalized] Americans.”

The study identified 5 key findings related to health disparities in the US. Firstly, the AIAN population in the West is experiencing a severe health crisis, with declining life expectancy due to systemic issues. Secondly, while Black Americans made progress in life expectancy during the early 2000s, these gains have stalled in recent years. Thirdly, Latino Americans exhibit significant regional disparities, particularly in the Southwest. Fourthly, the COVID-19 pandemic exacerbated life expectancy declines among AIAN, Black, and Latino populations, driven by systemic racism and socioeconomic inequities. Finally, there are notable inequalities among White Americans, especially in Appalachia and the Lower Mississippi Valley, where life expectancy has stagnated or declined, emphasizing the influence of geography and income on health outcomes.♦

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Decisions and Precision in Value-Based Cancer Care

HAYDEN E. KLEIN

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ELKHANANY



BRISBIN



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PRIMEAUX



PATEL



MCGUGAN



LIN



ESCUDIER



MAMA

PRECISION MEDICINE IS transforming cancer care by tailoring treatments to the genetic profiles of patients, but logistical and systemic barriers persist, particularly in implementing widespread biomarker testing. A recent panel at the Institute for Value-Based Medicine (IVBM) event in Houston, Texas, explored how academic and community oncology practices are navigating these challenges, with speakers sharing insights into improving access, turnaround times, and collaboration.

The integration of precision medicine into oncology practices remains inconsistent, largely due to varying workflows and infrastructure. “From a community oncology perspective...each hospital [often] does their physician medicine a little bit different, so it’s not like a 1 size fits all,” said Bhuvana Sagar, MD, a practicing oncologist at Oncology Consultants. Sagar highlighted the delays that often occur in community settings, such as deciding when to order tests and addressing issues such as insufficient tissue samples.

Academic centers face different barriers in implementing precision oncology care, including bureaucracy and strict guidelines for off-label drug use. “The definition of precision is really getting the right drug for the right patient at the right time, and I think that sometimes academic medicine is more governed by more bureaucratic things than actual private practice,” Ahmed Elkhanany, MD, an assistant professor of medicine at Baylor College of Medicine. Despite these constraints, however, academic institutions benefit from robust frameworks for conducting clinical trials and utilizing next-generation sequencing (NGS).

Turnaround times for biomarker testing are a significant concern in both community and academic settings. These delays can impact treatment decisions, particularly in urgent cases such as advanced lung cancer. With this in mind, Sagar noted that partnerships with labs are key, explaining that proactive communication about insufficient samples can prevent delays.

Lori Brisbin, MS, vice president of precision medicine at Texas Oncology, described her organization’s success in leveraging information technology tools to streamline workflows, noting how Texas Oncology implemented a cloud-based database that allows physicians to access real-time test results and identify patients who may qualify for clinical trials. It also helps physicians track patients with specific mutations, making it easier to match them with appropriate trials or treatments. According to Brisbin, this has led to improved speed and accuracy of clinical trial enrollment, ensuring that eligible patients receive timely care.

Effective communication and data integration are also critical factors in advancing precision medicine. Elkhanany emphasized the importance of having a dedicated team to manage workflows and coordinate with external vendors. He shared a recent example where a lab alerted him to a patient with a rare *TP53* mutation, enabling quick enrollment in a clinical trial. “This kind of integration is what we hope for,” he said, underscoring the value of real-time data sharing.

Access to biomarker testing is often limited by payer policies and financial barriers, which can exacerbate disparities in

cancer care. Sagar emphasized that coverage policies are key to ensuring timely and equitable access, pointing to her previous work with insurers to streamline prior authorization processes for NGS. Brisbin highlighted a new law in Texas, which passed with bipartisan support, that mandates insurance coverage for broad NGS testing in metastatic solid tumors. This law removes the fear of patients facing a \$3000 bill and encourages providers to order the necessary tests. However, she cautioned that payer partnerships must include clear guidelines to prevent billing issues and ensure financial assistance for patients.

The panelists agreed that although policies such as the Texas law mentioned above are steps in the right direction, more work—especially alignment between payer policies and clinical guidelines—is needed to standardize precision oncology protocols across the country and improve both the quality and cost of care.

Advancing Treatment Pathways for Multiple Myeloma

The treatment landscape for multiple myeloma has undergone a dramatic evolution in recent years, driven by innovative therapies and the growing complexity of treatment regimens. This evolving landscape prompted a discussion among another set of panelists on how advancements such as quadruplet therapies, anti-CD38 monoclonal antibodies, and chimeric antigen receptor (CAR) T-cell therapy have reshaped both first-line and relapsed/refractory settings.

Multiple myeloma treatment has become increasingly complex, with the field moving from doublets to triplets and now to quadruplet-based induction therapy as the standard of care. According to the panelists, data from recent clinical trials, including PERSEUS (NCT03710603)¹, GRIFFIN (NCT02874742)², and IMROZ (NCT03319667)³, have solidified the role of quadruplet regimens in both transplant-eligible and -ineligible patients. Adeel Khan, MD, MPH, MS, an assistant professor of internal medicine and director of myeloma epidemiology research at UT Southwestern Medical Center, described this evolution as an “embarrassment of riches.”

“The addition of more and more drugs to existing regimens and the fact that there are further drugs in the pipeline means the permutations have gotten pretty complicated,” Khan said. “So, the mantra of how to treat has been to add another drug in, add another drug in. In general, it’s actually proven to be very efficacious, so I don’t think there’s anything necessarily harmful to it, but I do think it has added a lot of complexity to the landscape.”

The introduction of anti-CD38 monoclonal antibodies, notably daratumumab (Darzalex) and isatuximab (Sarclisa), has been transformative for improving progression-free survival and achieving minimal residual disease (MRD) negativity. “We’re looking at almost 90 months or so, which is unprecedented for a transplant-ineligible patient population,” said Hans Lee, MD, director of multiple myeloma clinical research and associate professor of lymphoma and myeloma at The University of Texas MD Anderson Cancer Center (MD Anderson). “This would be unheard of 5 to 10 years ago.”

Brian Primeaux, PharmD, BCOP, a clinical manager and clinical pharmacy specialist at MD Anderson, praised the development of subcutaneous formulations of these therapies, noting their

benefits for both patients and providers. Subcutaneous regimens reduce the need for intravenous access and have limited toxicities, improving both patient convenience and safety, he explained.

MRD testing is increasingly used to guide treatment decisions and align with value-based care principles, as MRD results help determine whether to pursue up-front transplant or delay it in standard-risk patients. During the discussion, Lee noted how MRD negativity allows for discussions on deferring transplants and even deescalating maintenance therapy, which ultimately reduces costs and adverse effects. However, Khan urged caution in overrelying on MRD as a sole end point.

“If someone flips from MRD negative to positive but biochemically [and clinically are] still doing well...it does beg the question: Is that still meaningful?” he said. “I tend to think of [MRD testing] as 1 tool in the toolbox; [it’s] by no means the end all be all.”

As novel therapies such as CAR T-cell therapy and bispecific antibodies revolutionize the management of relapsed/refractory multiple myeloma, long-term cost-effectiveness remains a critical concern. Panelists highlighted the importance of prioritizing CAR T-cell therapy for high-risk patients, especially those with early disease progression, as administering it earlier in patients with lower disease burden can result in better outcomes and fewer toxicities. They also praised bispecific antibodies as “off-the-shelf” therapies with significant potential to achieve deep and durable responses.

“The addition of more and more drugs to existing regimens and the fact that there are further drugs in the pipeline means the permutations have gotten pretty complicated. So, the mantra of how to treat has been to add another drug in, add another drug in. In general, it’s actually proven to be very efficacious, so I don’t think there’s anything necessarily harmful to it, but I do think it has added a lot of complexity to the landscape.”

— Adeel Khan, MD, MPH, MS,
assistant professor, internal medicine;
director, myeloma epidemiology research,
University of Texas Southwestern Medical Center

Pharmacy Decision-Making in Value-Based Cancer Care

As value-based care models continue to shape oncology, pharmacy teams play a pivotal role in navigating site-of-care mandates, managing treatment costs, and optimizing workflows. At the IVBM event, panelists shared insights into strategies for minimizing fragmented care, improving equity, and supporting novel therapies such as bispecific antibodies and CAR T-cell treatments.

The shift to alternative care models, such as home or outpatient clinics, has introduced both opportunities and challenges. Site-of-care mandates can reduce travel burdens for patients and improve adherence, but they also pose the risk of fragmented care due to limited communication across providers. Additionally, prescribers may lack authority at infusion centers, and home health services often require third-party pharmacies, adding extra layers of complexity and warranting streamlined processes to ensure patient safety and continuity.

When asked how their practice is providing value through its pharmacy service models, Binita Patel, PharmD, MS, CPEL, vice president of pharmacy services at Memorial Hermann Health System, detailed a hub-and-spoke model that her institution is developing to reduce fragmented care. With this strategy, outpatient clinics, home infusion pharmacies, and hospital-based infusion clinics are tied to the same electronic medical record system, with pharmacists embedded in both inpatient and outpatient clinics. “Having those different types of care settings within your own health system allows you to provide the highest level of care with less fragmentation,” she said.

Megan McGugan, PharmD, MS, BCPS, a specialty pharmacy manager at MD Anderson, and Karen Wang, PharmD, BCOP, a clinical pharmacy specialist in thoracic/head and neck medical oncology at MD Anderson, highlighted how their practice is addressing care gaps by launching a prior authorization pilot and implementing a drug donation program. This initiative enables the repurposing of unopened medications to help patients facing financial or logistical barriers, improving equity and access to costly therapies.

Wang further emphasized the importance of follow-up phone calls in ambulatory clinics, which monitor patient well-being after immunotherapy or chemotherapy. These calls also provide education and help reduce readmission rates by improving toxicity management and home care preparedness. At Houston Methodist Hospital, Karen Abboud, PharmD, BCPS, BCOP, a pharmacy clinical specialist in solid tumors, explained how using a pilot program with collaborative practice agreements allows pharmacists to manage supportive care autonomously, therefore reducing physicians’ workloads while ensuring timely, expert care for patients.

The Impact of Social Determinants of Health on Cancer Care

Conversations around social determinants of health (SDOH) are common at IVBM events across a range of disease types. At the Houston regional event, panelists discussed how SDOH factors such as transportation, financial toxicity, and systemic inequities hinder equitable cancer care and proposed solutions for creating a more inclusive health care system.

“I think of [SDOH] like a chain, and the chain is only as strong as its weakest link,” said John Lin, MD, MSHP, a medical oncologist and assistant professor of health services research at MD Anderson, explaining how factors such as food insecurity, transportation barriers, and medical mistrust can prevent patients from accessing necessary treatments. “There are so many different facets of this, and any 1 of them could be the breaking point at which this patient is not getting their care because of that 1 thing.”

Susan Escudier, MD, FACP, a medical oncologist and vice president of value-based care and regional medical director at Texas Oncology, added that a patient’s zip code can often predict their cancer prognosis. Radiation treatments, for instance, require daily visits, but transportation costs and time off work create significant burdens. These challenges can be compounded by language gaps, education barriers, and limited access to public health resources, particularly in rural areas.

Insurance coverage—or lack thereof—is another major contributor to disparities in cancer care. Lin highlighted that even patients with Medicare can face unaffordable out-of-pocket costs, particularly for Part D medications. He also cited research showing improved cancer mortality rates in states that expanded Medicaid,⁴ but he emphasized that commercially insured patients often experience better outcomes than those on Medicaid.

To address these disparities and others, the panelists agreed that systemic changes and targeted interventions are necessary. Lin, who advocated for widespread implementation of patient navigators, shared how care navigation has consistently proven to reduce disparities by providing patients with tailored support. Scherezade Mama, DrPH, associate professor of health disparities research at MD Anderson, echoed the sentiment, saying that navigators help patients manage complex systems and are especially effective in improving clinical trial enrollment among underrepresented populations.

Escudier emphasized the importance of data collection on SDOH, as mandated by the Oncology Care Model. However, she also stressed the need for actionable follow-up. “We had to quadruple the number of social workers we had, but we don’t have any more resources to deal with it,” she said.

Looking ahead, the panelists called for policy reforms to better support underserved communities and improve cancer care outcomes. ♦

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Communication Is Key in Era of Oncologist Shortages, Experts Say

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AS 2024 CAME TO A CLOSE, experts from the realms of oncology, pharmacy, and dermatology gathered to discuss avenues for elevating value in cancer care at *The American Journal of Managed Care's* final Institute for Value-Based Medicine event of the year, which was held on December 12, 2024, in Seattle, Washington. The session featured discussions about the concept of value in oncology, the importance of interdisciplinary collaboration, and the need to keep patients, their finances, and their well-being at the center of care.

When it comes to elevating value in cancer care, Sara J. Grethlein, MD, MBA, FACP, a medical oncologist and executive medical director at Seattle's Swedish Cancer Institute, placed streamlining payer–health system collaboration and balancing personalized care with clinical guidelines at the forefront. She outlined how duplicated work and needless competition, such as “AI fighting AI” during prior authorizations, unnecessarily bogs down patient care. “Why are we wasting resources? Why are we wasting time and treasure on fighting a battle where we have answers, and we know at the end of the day we're going to wind up covering what's on the [National Comprehensive Cancer Network] guidelines?”

Incorporating tools such as ClinPath can accelerate these processes, she added, as they include both cost factors and clinical guidelines in decision-making. As a result, health systems can effectively strike a balance between cost-conscious and evidence-based care.

“The problem with these guidelines is that most of the clinical care that we deliver just does not come in a textbook format,” an audience member said. “So, isn't relying on guidelines really taking the nuance out of medicine?”

Although Grethlein agreed, she stressed the workforce crisis currently happening in oncology: More clinicians are leaving and retiring from the field than are entering. Furthermore, data project a 40% increase in cancer care demand in the coming years. Relying on guidelines will play a big role in addressing these shortages and supporting team-based care among pharmacists, nurse practitioners, physician assistants, and others; however, guidelines should not be taken at face value, and there should always be room for questioning and flexibility. Clinicians know well that certain cases require more tailored care than guidelines can account for.

As the oncology workforce continues to evolve, anticipated demands in patient care underscore the need for a cultural shift in care delivery. Moving forward, partnerships that prioritize communication and complement one another's strengths, rather than offloading responsibilities entirely, are what will ensure that high-quality care remains the standard.

A panel of pharmacists built on Grethlein's points by highlighting the benefits of their multidisciplinary, integrative medicine service at the Fred Hutchinson Cancer Center (Fred Hutch). Beginning in 2018, the service has grown from 3 to 13 members, including embedded pharmacists, naturopathic doctors, and an acupuncturist, among other health professionals who provide patient-driven and evidence-based care.

“One of the benefits of having an integrative medicine service in your organization is [that] it's really easy for us to communicate with each other...[and] the patients,” said Rachel Feaster, PharmD, BCOP, BCPS, a clinical oncology pharmacist at Fred Hutch.

Ivan Huang, PharmD, BCOP, clinical oncology pharmacist, Fred Hutch, continued the discussion by highlighting the

potential of their recently implemented outpatient-specific model, for which value-based medicine has been a driving influence. “The several types of value that I see include patient value—how can we maximize their quality of life, financial value, and resource value,” he said.

The true purpose of the model is to optimize patient value by transitioning therapies that are commonly prescribed in inpatient settings (eg, bispecific antibodies) to outpatient care. This way, patients can be administered care in familiar settings with more consistent support and less stress, all while reducing hospitalization time and improving resource allocation, such as freeing up hospital beds. At the end of the day, Huang added, less time admitted to inpatient care also benefits patients financially.

Grace Baek, PharmD, a clinical pharmacist specializing in hematology at Fred Hutch, also spotlighted the growing interest in expanding programs like this to facilitate accessible care delivery in more rural and community settings. Calling back to Grethlein's talk, Baek reinforced how critical partnerships are “in terms of working with nursing colleagues on the clinical and infusion sides, working with physician champions and advanced practice providers to build a collaborative approach...[and] ensuring that there are no opportunities for things to fall through the cracks.”

As the evening concluded, skin cancer experts and the panel's lone dermatologist, Song Park, MD, assistant professor, Department of Dermatology, University of Washington Medicine/Fred Hutch, spotlighted the best practices in their field and their efforts to implement value-based care for more accessible, cost-friendly, and efficient therapies.

Sylvia Lee, MD, an oncologist and associate professor at the University of Washington Medicine, kickstarted the conversation by focusing on the value of tumor-infiltrating lymphocyte (TIL) therapy. “To be able to offer someone a 31% chance of response, with some having long-term responses, is pretty exciting and meaningful—especially for patients who have progressed on PD-1, CTLA-4, and BRAF therapies, essentially exhausting their treatment options,” Lee said.

However, TIL therapy's post-FDA approval integration came with its own set of challenges, as Lee detailed the extensive contract, legal, and pricing considerations that came into play. Furthermore, the involvement of numerous institutions left departments contending for certain control. Lee Cranmer, MD, PhD, FACP, of Fred Hutch, likened this experience and integrating the therapy regularly to “building a TILs machine. This is the hard part of building the machine.”

In this process, Cranmer hearkened back to the value of interdepartmental collaboration for elevating care delivery. “We were able to do it on the hospital floor, and that's what made all the difference. Having the nursing staff and the mid-levels be familiar with the therapy and allowing its administration on the floor, and transfer to the [intensive care unit] if you needed, made it economically viable,” he said.

Ineffective cancer care, Cranmer posed, is a primary concern due to the large financial burden it places on society at large, especially considering the US practice of investing large amounts of money into drugs and therapies that are yet to have proven benefits and may have toxic effects.

“Do you think it's worth it to have reduction in toxicity but similar efficacy, and do we have to pay double the cost of care to have some



GRETHLEIN



FEASTER



HUANG



BAEK



PARK



LEE



CRANMER



BHATIA

reduction in toxicity?” asked moderator Shailender Bhatia, MD, director, Melanoma and Renal Cancer team, and professor, Fred Hutch.

“I’m on the side of seeing those long-term [toxicities] as a dermatologist,” Park said as she argued that reducing toxicity is, in reality, a cost-saving venture. “Because when that kind of toxicity happens and no traditional drug works, then dermatologists apply for even more expensive drugs.” For this reason, Song asserted that more research efforts should be dedicated to exploring novel developments, such as tert-butyl acetate, that remain high cost and require appropriate treatment candidates.

Other perspectives explored by the evening’s panelists and audience members alike were the promises that artificial intelligence (AI) holds for oncology care; however, clinicians expressed a hesitancy to delve too deeply into this technology just yet. The inability to “see under the hood,” as Grethlein put it, and to understand how AI comes to conclusions has left many hesitant to place clinical decision-making into the hands of these systems. As this technology grows, there will be a need for refined guidelines and a deeper trust in AI processes, especially for patient cases that do not fit into the guidelines’ mold. ♦



A New Horizon: Precision Medicine and Value-Based Care in Lung, Gastric, and Sarcoma Cancers

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ADVANCEMENTS IN ONCOLOGY are transforming the way we diagnose, treat, and care for patients with cancer, offering a glimpse into a future where innovation and precision medicine take center stage. From the promise of liquid biopsies and personalized therapies to the challenges of integrating value-based care models, the oncology landscape is undergoing a profound evolution.

As novel treatments such as antibody-drug conjugates (ADCs) and T-cell receptor gene therapies emerge, the focus is shifting toward improving outcomes, optimizing patient selection, and addressing disparities in access to care. At the heart of these developments lies a shared goal: to redefine cancer care by combining cutting-edge science with a patient-centered approach that prioritizes equity and meaningful health outcomes.

Speakers at the Institute of Value-Based Medicine event in Tampa, Florida, on December 12, 2024, detailed how treatment, diagnosis, and value-based care strategies have developed across several key oncology sectors, including the treatment of gastric and lung cancer. Richard D. Kim, MD, service chief, Medical Gastrointestinal Oncology and senior member, Gastrointestinal Oncology Department at Moffitt, served as the evening’s chair.

Daniel Anaya Saenz, MD, a particle researcher and newly promoted department chair of gastric, intestinal surgical oncology, and gastroenterology at Moffitt Cancer Center, delivered a keynote address on the benefits and principles of value-based care. He expressed deep interest in care delivery models.

Anaya said that value-based care seeks to improve patient health outcomes relative to the cost of care, emphasizing patient outcomes over mere cost reduction. He advocated for a patient-centered care relationship model that measures meaningful outcomes beyond clinical results and called for cultural transformation within institutions to implement value-based care effectively.

The lecture addressed challenges in oncology, such as fragmented care that forces patients to navigate multiple systems and specialists. Anaya praised Moffitt’s integrated care model but noted that many regions still struggle with fragmentation. He highlighted the lack of transparency in real-life outcomes and underscored the need to address financial constraints and changing reimbursement models.

Anaya discussed the evolving health care environment, highlighting the demographic shift toward younger, more involved

oncology patients, as well as the older population that is growing in Florida. He noted the formation of health networks and the need for coordinated, nonfragmented care. He also touched on the evolution of payment models toward patient-centered approaches, emphasizing satisfaction and outcomes.

To build value-based care frameworks, Anaya outlined the importance of understanding shared health needs and introduced integrated practice units designed to address patient segments’ needs through standardized and systematic activities. He emphasized measuring factors impacting clinical outcomes and patient well-being, using data to negotiate with payers and implement value-based payment models.

Anaya shared real-life examples of value-based care in oncology. He recounted a 20-year-old initiative in the Veterans Affairs system, where a virtual tumor board improved survival rates for patients with colorectal cancer and hepatocellular carcinoma. He described the development of a multidisciplinary care program at Moffitt, which allowed patients to receive comprehensive evaluations and treatment plans in a single visit. This model led to faster treatment initiation and increased patient engagement, and it expanded capacity to include advanced practice providers, which significantly boosted new patient numbers.

In discussing cost measurement and value-based payment models, Anaya explained how Moffitt measures costs and outcomes to create systematic processes for care delivery. He provided an example comparing the costs of 2 surgeries for the same cancer, illustrating how higher-cost surgeries can deliver greater value. He described the development of an episode-of-care payment model that focuses on the patient journey, improving care and resource allocation.

Anaya concluded by summarizing the essential components of value-based care, emphasizing the importance of understanding patient needs, quality improvement, and integrated care frameworks. He also highlighted the benefits of value-based care, including improved quality, growth, innovation, and research, while advocating for financial payment models centered on the patient journey.

The gastroenterology session focused on advancements in gastrointestinal cancer treatment, highlighting value-based care and precision medicine. Tiago Biachi, MD, PhD, an associate member at Moffitt and an associate professor at the University of South Florida, discussed liquid biopsy, particularly circulating



PELLINI



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tumor DNA (ctDNA), for detecting minimal residual disease and resistance mechanisms, noting its high specificity but low sensitivity, which requires multiple draws.

Iman Imanirad, MD, an assistant member at Moffitt and a professor of oncology at the University of South Florida College of Medicine, emphasized precision medicine in colorectal cancer, focusing on *KRAS* mutations and targeted therapies. “Precision medicine is here to develop, validate, and predict biomarkers through diagnostics, general clients, somatic profiling, and liquid biopsies.... It aims to define parameters of care, optimize specific demographics, define the optimal use of technologies such as DNA analysis and liquid biopsies, and deliver the right treatment to the right person at the right time,” Imanirad said.

Mintallah Haider, MD, a medical oncologist and associate, Department of Gastrointestinal Oncology and the Neuroendocrine Tumor Program at Moffitt, highlighted novel treatments for endocrine tumors, including cabozantinib and peptide receptor radionuclide therapy (PRRT), showcasing their efficacy.

The session featured presentations on ctDNA’s clinical applications, including its role in guiding treatment through trials and complementing tissue-based next-generation sequencing. Imanirad detailed the impact that genetic mutations have on colorectal cancer treatment responses, whereas Haider explored advancements in treating neuroendocrine tumors with tyrosine kinase inhibitors and PRRT.

The thoracic oncology session highlighted advancements in lung cancer treatment. Edgardo S. Santos Castillero, MD, FACP, FASCO, a hematologist and medical oncologist at the Oncology Institute of Hope and Innovation and medical director for Broward County, Florida, discussed precision medicine’s impact, including checkpoint inhibitors, lung cancer vaccines, and bispecific antibodies, alongside technologies such as PET scans, artificial intelligence, and liquid biopsy for early detection and personalized treatment. He emphasized the need for better screening and equitable care.

Bruna Pellini, MD, an assistant member at the Department of Thoracic Oncology at Moffitt and an assistant professor at Morsani College of Medicine at the University of South Florida, focused on using ctDNA to monitor metastatic lung cancer treatment response,

presenting data on its prognostic value and the challenges of applying ctDNA assays across populations.

Sonam Puri, MD, a medical oncologist specializing in lung cancer at Moffitt, covered how ADCs and bispecific antibodies could be transformative therapies, discussing their mechanisms, clinical applications, and the importance of managing toxicities and optimizing patient selection. Future directions included bispecific ADCs, radionuclides, and combination therapies, with an emphasis on addressing disparities in cancer care.

The final session focused on the latest advancements in sarcoma treatment, with an emphasis on novel therapies and technologies. To start, Andrew Brohl, MD, a medical oncologist and physician-scientist at Moffitt, focused on sarcoma patient selection for immune checkpoint inhibitor therapy, exploring the criteria and considerations for optimizing patient response to these therapies. The session highlighted the latest advancements and strategies in treating sarcoma, aiming to improve patient care through innovation and precision medicine.

Mihaela Druta, MD, an assistant professor, Sarcoma Medical Oncology, discussed the potential of T-cell receptor gene therapy, highlighting its role in targeted treatment. She highlighted synovial sarcoma and its treatment options, the importance of value-driven cancer care, and advancements from clinical trials such as SPEARHEAD-1 (NCT04044768).¹ Druta also discussed progress in novel therapeutics for soft tissue sarcomas and emphasized collaboration and ongoing efforts in cancer research as essential for continued progress.

Lastly, Gina D’Amato, MD, a professor of clinical medicine and medical oncologist at the University of Miami Miller School of Medicine, presented advancements in early detection methods for sarcoma, emphasizing the importance of early diagnosis for improved outcomes. ♦

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Balancing Innovation and Equity in Oncology Value-Based Care: Panel Discussions

GIULIANA GROSSI

IVBM DALLAS



PATEL



KLEMOW

DURING A SERIES OF PANEL DISCUSSIONS featuring top experts from The University of Texas (UT) Southwestern Medical Center, Texas Oncology, and other institutions, breakthroughs in cancer treatment and care delivery took center stage January 16, 2025, at the Institute for Value-Based Medicine event in Dallas, Texas. From leveraging CDK4/6 inhibitors and genomics in breast cancer to advancing precision medicine in lung cancer, panelists examined how cutting-edge therapies are transforming outcomes. Discussions also delved into the complexities of value-based oncology care, the growing role of real-world data, and strategies to improve access to care in hematology. Across all sessions, a common theme emerged: the need to balance innovation with patient-centered, equitable, and sustainable care models.

“Innovations in Breast Cancer Treatment”

The panel, moderated by Ina Patel, DO, an assistant professor at UT Southwestern Medical Center, focused on several important topics in the management of early-stage and metastatic breast cancer. The first discussion centered around the use of CDK4/6 inhibitors as adjuvant therapy for hormone receptor (HR)-positive, HER2-negative early-stage breast cancer. The panelists highlighted the need to balance the potential benefits of agents such as abemaciclib (Verzenio) and ribociclib (Kisqali) with their adverse effect profiles and duration of treatment.

Dawn Klemow, MD, a medical oncologist at UT Southwestern Medical Center, explained the differences between both therapies and how treatment duration factors into her decision for each patient. Abemaciclib has been FDA approved for longer and is indicated for node-positive cancer, whereas ribociclib was recently

approved and provides a CDK4/6 treatment option for patients with node-negative cancer.

“If I’m very concerned about the potential risk for relapse, I definitely use the CDK4/6 inhibitor, and...you can see the criteria [for] who is eligible or not,” she said. “I know positive patients for [abemaciclib]; for that reason, it’s a year shorter duration of treatment. The important thing to remember when you think about the diarrhea is that [abemaciclib] works even at [a] low dose. It’s not necessary to give full-dose [abemaciclib], which is where you see most of the toxicity with diarrhea. So, [abemaciclib] is still my first choice unless they’re high risk [or] node negative, then it is ribociclib.”

Ribociclib stands out as the only CDK4/6 inhibitor with overall survival data, yet all 3 agents—ribociclib, palbociclib (Ibrance), and abemaciclib—have roles depending on patient profiles, according to Rochelle Horadam, RPh, BCOF, an oncology pharmacist at UT Southwestern Medical Center. Horadam prefers palbociclib for older patients with bone-only metastases because of its lower risk of liver toxicity, despite some manageable neutropenia. Abemaciclib, which is effective in both early-stage and metastatic breast cancer, offers flexibility at lower doses, although it may cause diarrhea and increase serum creatinine, requiring alternative renal function tests. Ribociclib, with a category 1 indication in the National Comprehensive Cancer Network (NCCN) guidelines, is effective but poses challenges with liver toxicity, drug interactions, and the need for electrocardiogram monitoring.

“We know that cost of care is really high. Outcomes for patients, especially in the United States, are lagging other countries. There are a lot of issues with inappropriate treatment at the end of life, [such as] inappropriate therapies being given [and] other decisions driving what we do outside of value. So, as you’re thinking about value-based care models, what metrics and outcomes do you think are important that we incorporate into those?”

—Lalan Wilfong, MD,
Senior vice president, Value-Based Care
Thyme Care

“Drug interactions...[are] a huge part of my job, having to identify them and patients [who] are on antidepressants, which a lot of these patients are on. It’s sometimes difficult to manage some of the interactions,” Horadam said. “So, picking the appropriate drug...[is] really based on the patient profile, including performance status.”

Next, Patel focused the discussion on genomic integration. For premenopausal patients receiving ribociclib, ovarian suppression is necessary to pair the treatment with an aromatase inhibitor effectively, she explained. Regarding integrating genomics into breast cancer care, the panelists discussed the critical role of molecular biomarkers in guiding treatment strategies. In metastatic breast cancer, next-generation sequencing (NGS) for targetable mutations is often performed at the time of first metastatic diagnosis to optimize initial treatment plans. However, some clinicians may delay testing until disease progression or after a biopsy of the progression site, depending on the clinical context.

“This is interesting because most [patients with] metastatic breast cancer these days are going through 5, 6, [or] 7 lines of treatment,” said Ashwani K. Agarwal, MD, a medical oncologist and hematologist with Texas Oncology. “It’s become a game of chess.”

Agarwal explained that at Texas Oncology, all patients with metastatic breast cancer undergo up-front biomarker testing and additional testing at any point of disease progression. The team prioritizes accessible biopsy sites, such as liver metastases, while avoiding lung biopsies because of the risk of pneumothorax. Liquid biopsies are used aggressively, with tests such as Guardant360 performed every 3 to 6 months to monitor for key mutations such as *ESR1* and *PIK3CA*. Regular liquid biopsies help detect mutations early, informing treatment decisions and guiding adjustments to therapy over time.

The panelists emphasized the value of comprehensive NGS, both at diagnosis and at progression, to identify targetable mutations and guide treatment decisions, including access to clinical trials. They also noted the challenges in obtaining sufficient tissue for testing and the growing role of liquid biopsies in this setting.

Regarding the use of antibody-drug conjugates in breast cancer, the speakers highlighted their evolving role, particularly in HR-positive and ultralow HR-positive disease. They discussed the need to balance efficacy and toxicity when selecting targeted therapies and the challenges in accurately identifying ultralow HR-positive patients.

Finally, the panel touched on promising research areas in metastatic breast cancer, including the shift toward more targeted treatments, the potential of chimeric antigen receptor T-cell therapies and vaccines, and the importance of deescalating chemotherapy cycles to improve patient outcomes and quality of life.

“We [always] try to evaluate bone marrow and other avenues in which we could target therapy,” Patel said. “I know there’s [also] always talk of vaccines, particularly in the triple-negative space for breast cancer, which has shown some promise of preventing recurrence from happening or progression in metastatic disease. I know we have [the FLAMINGO-01] trial (NCT05232916) at [the University of Texas], where we’re looking at vaccines to prevent HER2-positive disease after someone has already done chemo for HER2 disease.”

The following panel discussion, “Access to Care in Hematology,” touched on this topic.

Access to Care in Hematology

The panel, moderated by Farrukh T. Awan, MD, MS, MBA, professor, Department of Internal Medicine, UT Southwestern Medical Center, focused on the challenges and opportunities in defining clinically meaningful end points for rare hematologic diseases, as well as the role of real-world data and value-based care models in oncology.

The panelists, Hycienth Ahaneku, MD, PhD, of Texas Oncology, and from the UT Southwestern Medical Center, Adeel Khan, MD, MPH, MS; and Praveen Ramakrishnan, MD, discussed the difficulties in establishing appropriate end points for rare diseases, where traditional measures such as overall survival or progression-free survival may not be feasible or practical.

Awan began by sharing a story about his early experience with systemic mastocytosis, a rare disease he encountered shortly after completing training. Despite limited knowledge about the condition at the time, he became deeply involved in a trial that ultimately led to the approval of midostaurin (Rydapt). He highlighted the difficulties of defining meaningful end points for rare diseases, such as addressing quality of life, symptom burden, and specific issues such as rashes or anaphylactic reactions.

The bar for developing a trial is higher than it once was, Ramakrishnan said. “You have to be a kind of center of excellence to pull people in and have meaningful end points. Some of these may not be just scans alone... Response rates you can’t really look at, like survival, are the only end point in some of these rare diseases... To get these drugs approved, you need to have novel solutions and novel targets as your end points. [Don’t] just focus on response rates or just survival. Patient-reported outcomes...and improvement in quality of life are paramount to some of these disorders.”

The panel also highlighted the growing influence of real-world data in clinical practice and their impact on NCCN guidelines. Some noted that the rigidity of guidelines can sometimes limit the



HORADAM



AGARWAL



AWAN



KHAN



WILFONG



RUSSO



DOWELL



PRAKASH

clinician's ability to provide personalized, patient-centered care, particularly for complex or rare conditions. The panelists stressed the need for more nimble and flexible approaches that prioritize the individual patient's needs.

Ahaneku shared that he's happy that NCCN is looking into real-world data because the data can be translated into the practice of clinicians who see patients in the community. "Those things that come back from phase 4 clinical trials—the [adverse] effects profile and things like that—eventually help to refine how we practice, especially with respect to [the adverse] effects profile," he said. "So, doing more real-world data evaluation helps the clinicians better in my estimation. I'm not saying that [phase 3 clinical trials] are not important, but real-world data and the feedback we get from them enhances our management of patients a lot."

Regarding the Inflation Reduction Act (IRA) and its potential impact on health care, the panelists reflected on how it has helped improve access to targeted therapies for their patients, particularly those on Medicare or Medicaid. They discussed the potential benefits of the IRA's provisions, such as Medicare's ability to negotiate drug prices and the challenges in balancing cost-effectiveness with patient-centered care.

Kahn addressed CMS's long-standing inability to negotiate prices and highlighted the tension between pharmaceutical companies' need for profitability and patients' need for affordable access. Using lenalidomide as an example, he pointed out that even after becoming generic, the drug remains expensive due to factors such as the Risk Evaluation and Mitigation Strategy program and historical context dating back to thalidomide. He pointed out the phased model used by the UK's National Health Service, which structures price reductions over time instead of the sharp transitions seen in the US.

"Instead of the brand-name generic, with the sharp transition that we have here in the US, a faded model allowed for more equitable pricing and ultimately for expanded access," Kahn said. "That seems so simple and so brilliant, but we just haven't done it here."

The panel also delved into the complexities of value-based care models in oncology, with the panelists sharing their experiences in navigating the transition from fee-for-service to value-based reimbursement. They discussed the difficulties in managing both payment structures simultaneously and the importance of maintaining a consistent, high-quality standard of care across all patient populations.

Value-Based Oncology Care Within the US

Lalan Wilfong, MD, senior vice president of value-based care at Thyme Care, moderated a conversation on value-based care in the US. The discussion also featured Travis Brewer, vice president of payer and public health strategy/relations for Texas Oncology; R. Steven Paulson, MD, CEO of Texas Oncology; and Barry Russo, MBA, CEO of The Center for Cancer and Blood Disorders. They discussed the opportunities and challenges in shifting from fee-for-service to value-based care models.

One of the primary challenges Wilfong first brought up was the need to manage both fee-for-service and value-based care models simultaneously within a practice. "We know that cost of care is really high. Outcomes for patients, especially in the United States, are lagging other countries. There are a lot of issues with inappropriate treatment at the end of life, [such as] inappropriate therapies being given [and] other decisions driving what we do outside of value," he said. "So, as you're thinking about value-based care models, what metrics and outcomes do you think are important that we incorporate into those?"

In response, Russo emphasized the importance of focusing on outcomes, including efficacy, toxicity, and financial toxicity. The use of pathways and the need to consider the cost of treatments, in addition to their clinical efficacy, when making treatment decisions was also discussed.

"The barometers of looking at outcomes are really about overall survival, progression-free survival, quality-of-life metrics, and such," Paulson said. "Using patient-generated [electronic patient-reported outcomes] to assess their overall quality of life is incredibly important."

The panel also addressed the complexity of value-based care models in oncology. Brewer noted that many previous attempts at implementing these models in the oncology space had failed due to overly ambitious goals. The panelists suggested that a more modular, disease-specific approach may be more successful in the future.

"I mentioned before we're well positioned once a model comes down the path because I think payers, too, are primarily focused on cost when you're talking

about a purely commercial book of business," Brewer said. "I think they do focus a little more on quality when you get into the managed Medicare population, [the] reason being [that] those populations are a little stickier; the payers tend to retain those patients year over year."

Regarding the role of third-party value-based care enablers, the potential value these entities can provide in bridging the gap between payers and practices was acknowledged, particularly in helping to manage risk and develop appropriate tools and programs. The discussion also touched on the importance of real-world data and their impact on clinical practice and NCCN guidelines. The panelists offered their perspectives on the need for nimbler and patient-centered approaches to clinical decision-making, as the rigidity of guidelines can sometimes limit clinicians' ability to provide personalized care.

Advancements in Precision Medicine in Lung Cancer

The event's final discussion observed the impact of precision medicine on the treatment of non-small cell lung cancer (NSCLC). Moderated by Lori Brisbin, MS, vice president of precision medicine at Texas Oncology, the conversation highlighted the significant advancements in NSCLC treatment, particularly the role of immunotherapy and targeted therapies.

Jonathan Dowell, MD, a professor of internal medicine at UT Southwestern Medical Center, and Sucharu Prakash, MD, a board member for Texas Oncology, explored how immunotherapy has dramatically changed the landscape for patients with late-stage disease, as well as in earlier-stage settings, including neoadjuvant and adjuvant therapy.

"[Immunotherapy has] dramatically changed the landscape for not only [patients with NSCLC] with late-stage disease but [also at] earlier stage, including neoadjuvant therapy," Dowell said.

In addition, patients with small cell lung cancer are responding to immunotherapy. "We're seeing patients, not as many as we'd like, who have durable responses and long-term remissions that we never saw prior to the advent of prior to the advent of immunotherapy," Dowell said.

Another topic in this discussion was NGS in identifying targetable mutations in NSCLC, such as *EGFR*, *ALK*, and *KRAS*. Prakash explained why comprehensive NGS testing should be performed at diagnosis, as these molecular profiles can guide treatment decisions and help avoid the use of ineffective or potentially harmful therapies, such as immunotherapy in *EGFR*-mutant patients.

"Every advanced lung cancer or any solid tumor...should get a full panel [or] broad panel, NGS test," he said. "Why is that important? Because you don't want to miss any targetable mutation that could have a therapy or a clinical trial that a patient might be able to go on, right? And it costs the same."

When addressing the challenges of obtaining sufficient tissue for NGS testing and the growing role of liquid biopsies, the panelists noted that liquid biopsies can provide a broader view of tumor heterogeneity and help expedite treatment decisions, particularly in cases where tissue is limited or difficult to obtain.

Regarding the timing of molecular testing, the panelists unanimously recommended testing as soon as possible upon diagnosis, before initiating any therapy, to ensure the most informed treatment decisions.

Patient education and perceptions can influence treatment decisions, particularly the tendency for patients to request immunotherapy based on media exposure, even when their molecular profile may indicate a more appropriate targeted therapy. During this discussion, the importance of thorough patient education was emphasized to ensure alignment between the recommended treatment and the patient's understanding of the disease and available options.

Overall, the panel offered perspectives on the rapidly evolving field of precision medicine in lung cancer, highlighting the critical role of comprehensive molecular testing, the growing use of liquid biopsies, and the need for patient-centered, data-driven treatment decisions.

Driving Progress Through Collaboration in Oncology

Beyond the significant advancements in oncology, including precision medicine for lung cancer and innovative therapies for breast cancer and hematology, the event's discussions delved into the need to integrate cutting-edge treatments such as CDK4/6 inhibitors and NGS while addressing challenges such as toxicity and equitable access to care. The perspectives reflected a commitment to balancing clinical innovation with patient-centered solutions, paving the way for more personalized and effective cancer care. ♦

Once Again, CMS Selects McKesson's Practice Insights as a Qualified Clinical Data Registry

MARY CAFFREY

FOR THE NINTH CONSECUTIVE YEAR, CMS has selected McKesson as a Qualified Clinical Data Registry (QCDR) approved to take part in the Merit-Based Incentive Payment System (MIPS). This means McKesson is qualified to collect and report clinical data from clinicians taking part in the CMS Quality Payment Program, which was created in 2015 to reward high-value practices under the Medicare Access and CHIP Reauthorization Act.¹

According to a statement from McKesson, the designation permits data collection through the company's iKnowMed electronic health record (EHR) and the Practice Insights performance analytics tool, which provides insights through McKesson's Ontada business. The designation renewal allows practices that use the iKnowMed EHR to submit data for MIPS and QCDR reporting directly to CMS without using another third-party vendor.

"McKesson is committed to providing actionable insights to community oncology practices that can empower them to improve patient care, reduce practice burden, and grow access to care in the community setting," Jason Hammonds, chief operating officer of oncology and specialty at McKesson, said in the statement. "As a 2025 QCDR, Practice Insights enables providers to easily gather and report quality measures to CMS while offering ready access to practice data and analytics to help them improve operations and patient care."²

Practice Insights allows clinicians to submit data on 9 oncology-specific QCDR measures, including 7 developed with input from community physicians in The US Oncology Network, which are listed below²:

- Resolution or improvement of a health-related social need (HRSN)
- Advanced care planning in patients with metastatic cancer
- Hepatitis B serology testing and prophylactic treatment prior to receiving anti-CD20-targeting drugs
- Patient-reported pain improvement
- Supportive care drug utilization in last 14 days of life
- Mutation testing for stage IV lung cancer completed prior to the start of targeted therapy
- Utilization of prophylactic granulocyte colony-stimulating factor (G-CSF) for patients with cancer receiving low-risk chemotherapy

Two other measures were developed by the American Society of Clinical Oncology and have been approved for the third year:

- Antiemetic therapy for low- and minimal-emetic risk antineoplastic agents in the infusion center—avoidance of overuse
- Appropriate antiemetic therapy for high- and moderate-emetic risk antineoplastic agents in the infusion center

In addition, CMS selected 2 McKesson measures for inclusion in the 2024 Advancing Cancer Care MIPS Value Pathways (MVPs): mutation testing for stage IV lung cancer and utilization of prophylactic G-CSF for patients receiving low-risk chemotherapy. Practice Insights is the only QCDR that has had measures selected for inclusion in the Advancing Cancer Care MVPs.²

Officials noted the new patient-reported outcomes measure that will assess outcomes associated with addressing HRSNs. Their

statement described the McKesson measure as the first HRSN measure to examine whether issues are resolved after being identified.

"McKesson's measure goes full circle, enabling clinicians to not only identify needs but also efficiently track and report results," Erin Crum, MPH, senior director of quality strategy and innovation at McKesson and The US Oncology Network, said in the statement.²

This new measure is especially important in helping practices comply with the Enhancing Oncology Model (EOM) requirements, which call for practices to assess HRSNs and devise a plan to address them.³ More than 70% of the clinicians in The US Oncology Network are taking part in the EOM.⁴

The American Journal of Managed Care (AJMC) asked Crum to elaborate on the success of the first year of use of the HRSN measure; she answered the following questions. For more information, she referred to a commentary published in October 2024 in *AJMC's* sister publication, *OncologyLive*[®].⁵

AJMC: Can you characterize the status of the HRSN measure that assesses whether HRSNs were resolved?

CRUM: The measure is slated for release in the next month. We will be able to track resolution [and] improvement across all iKnowMed users, The US Oncology Network practices, individual practices, and individual clinicians.

AJMC: How will patients and/or patient encounters be assessed?

CRUM: The measure utilizes the National Comprehensive Cancer Network [NCCN] Distress Thermometer.⁶ This has been integrated into iKnowMed and Ontada Health. Screening for [HRSNs] is becoming common practice across The US Oncology Network practices and is a key requirement of the EOM.

AJMC: Can the measure track an individual patient's journey? For example, can the practice tell whether a patient initially asks for housing or food and later seeks assistance, such as counseling?

CRUM: The measure complements the NCCN distress dashboard found within our Practice Insights QCDR, which provides the patient history associated with all screens. It is possible to see the patient's journey over time, related to areas of [HRSNs] and distress level within iKnowMed near the point-of-care as well.

AJMC: What kind of qualitative feedback did you get from practices about using this measure?

CRUM: We engaged a multidisciplinary team of clinicians, social workers, quality program leads, technology experts, and quality measure development experts to inform measure development through a formal work group approach. Focusing on patient-reported outcomes was critical and, in many ways, more feasible



CRUM

Erin Crum, MPH, senior director, quality strategy and innovation, McKesson and The US Oncology Network.



HAMMONDS

Jason Hammonds, chief operating officer, oncology and specialty, McKesson.

[because] tracking referrals and interventions are challenging when practices have the option to use a variety of outside tools, services, and systems.

AJMC: Does McKesson anticipate any fine-tuning of this measure going forward?

CRUM: We will continue to engage clinicians in The US Oncology Network for feedback to ensure the measure is meaningful and drives anticipated improvements in care to meet patient needs. We are also exploring integration with Findhelp,⁷ which could provide additional insight into the patient care journey and enable greater insight as to which interventions or community resources are truly impactful to resolve patients' [HRSNs]. ♦

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SPOTLIGHT



COA Readies for \$2000 OOP Cap, "Smoothing" Under IRA

Produced by Mary Caffrey



ALBERTO

JUDITH ALBERTO, MHA, RPH, BCOP, director of clinical initiatives, Community Oncology Alliance.

THE INFLATION REDUCTION ACT (IRA) features a pair of consumer-friendly provisions that took effect January 1, 2025, designed to save Medicare beneficiaries money and make it easier for them to budget for their prescription drugs. In addition, the despised "donut hole" goes away this year. The first change is an annual out-of-pocket cap of \$2000 on Part D drugs; however, the less talked about provisions call for plans to limit the benefit to prescriptions on formulary unless physicians obtain an exception.¹ The second provision is the "smoothing" benefit, which allows beneficiaries to pay their annual deductible in monthly installments.² These benefits could make a huge difference for the older population who rely on high-cost cancer therapies. However, according to Judith Alberto, MHA, RPh, BCOP, director of clinical initiatives for the Community Oncology Alliance (COA), administering them will require education for patients, practices, and pharmacists. Alberto spoke about the implementation of the IRA provisions during a visit with *Evidence-Based Oncology (EBO)* in our offices in Cranbury, New Jersey.

This transcript is lightly edited for clarity.

EBO: What potential challenges do you see in implementing the \$2000 out-of-pocket cap, or the "smoothing" provision, of the IRA?

ALBERTO: One of the things that concerns us is if a patient misses 2 payments, once they've enrolled in this [smoothing] program, they will be omitted from the program. They will not be able to continue. So, we're going to monitor what that looks like when a patient comes in

[and] how the pharmacist is dealing with that because we don't know what that will look like. We don't know what information the patient will get. That's something that we're keeping a very close eye on. Patients could choose to enroll later, so if they don't enroll with their first few prescriptions but decide to [enroll] later, then we're going to have to look at those financial calculations, making sure the patient understands them. It could be very complex. I think the pharmacist is going to be in a position to explain that to [the patients] and educate them. We're going to monitor what patients know and how the pharmacies are educating them, and we hope to be able to share that with all our practices as we go. As we learn more and things become more apparent, we'll continue to pass that information on and make sure everybody is in the know.

EBO: What steps has the COA taken to educate its members ahead of the implementation of these IRA provisions?

ALBERTO: Patients [and our care teams] will need to be educated.... [The] COA had done a webinar about 2 months ago where we brought our practices together to discuss this. We had some directors of pharmacy on our call so they could share with us how they plan to implement this. It will require resources from the practice; all practices are doing things slightly differently. Some are preparing sheets of paper to...hand out to their patients [who] are likely to benefit from the service. Some are handling this as they come in for their new prescription starting January 1, but it will require extra resources. CMS has some very good modules on their website that help to educate [patients]. A lot of pharmaceutical companies [and group purchasing organizations] are also providing education.... [The] COA will continue to keep an eye on this, and as we continue through the first quarter of 2025 and we understand more of what the implications may be to patients and their providers, we will offer additional education. ♦

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Future Breast Cancer Treatments: SERDs, Biomarkers

INTERVIEW BY CAMERON SANTORO

MABEL MARDONES, MD, board-certified medical oncologist and hematologist with an advanced subspecialty in breast cancer at Rocky Mountain Cancer Centers, led a discussion on new treatments for hormone receptor–positive (HR+)/HER2– breast cancer at the Denver Regional Institute for Value-Based Medicine.



MARDONES

Mardones highlighted in an interview with *The American Journal of Managed Care (AJMC)* the growing issue of drug resistance in HR+/HER2– breast cancer. She emphasized the need for biomarkers to identify patients who could benefit from more aggressive therapies, such as triplet therapy. She also discussed the promising potential of selective estrogen receptor degraders (SERDs), which may replace aromatase inhibitors as the standard of care due to their superior efficacy and reduced adverse effects.

This transcript was lightly edited for clarity.

AJMC: How are researchers addressing the challenges of drug resistance and recurrence in HR+/HER2– breast cancer?

MARDONES: With the inavolisib approval, there's the concept that, obviously, many patients are, in fact, endocrine-resistant and will become endocrine-resistant. This is not likely early on in the course of their treatment, but likely somewhere around years 5 through 10 or beyond. These are patients [whose diseases] metastasize and are resistant to an aromatase inhibitor.

I think that being forward thinkers and thinking ahead of the menu of choices we already have, and using biomarkers like this trial did. The patients with a *PIK3CA* mutation ho progress on aromatase inhibitors within a year are the patients who are going to get a triplet therapy, so escalate therapy in those [patients] who are truly endocrine-resistant.

There are a lot of challenges in sequencing that still remain today that I think are not answered. I think we have a lot of choices out, but then we're left with, "How do we choose one agent over another?" I think that speaks to the testament of how quickly the FDA is approving these agents, the clinical trials, and how robust they

have been, but that leaves us in the clinic with challenges.

AJMC: In your opinion, what are the areas of research that may lead to significant breakthroughs in the treatment of HR+/HER2– breast cancer in the next decade?

MARDONES: We have a variety of menus in our current treatment options with the oral SERDs. I tell my patients this; we've made it known that SERDs are superior to our most potent injection, which is Faslodex [fulvestrant] in the metastatic setting. There's no reason to believe that SERDS are not going to be more effective than an aromatase inhibitor.

If we look at just the trajectory of how tamoxifen beat aromatase inhibitors, now we have this new wave of options. I do think that SERDs will replace aromatase inhibitors probably in the next 10 years; whether that's only in the high-risk population or not is to be determined.

But these are the trials that are now being done in high-risk women and in high-risk women who are switching from an aromatase inhibitor to a SERD after 2 to 5 years.

I think probably the biggest thing or selling point of these SERDs is the fact that arthralgias and joint pain, which seems to be probably the top-line concern and No. 1 reason for discontinuation of aromatase inhibitors, is a whole lot less—that we've noted so far. That's been encouraging, and we remain optimistic that, hopefully, the compliance level of adjuvant endocrine therapy will rise as we bring on better choices but less toxic choices as well. ♦

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SPOTLIGHT

The Importance of Symptomatic Improvement in MPN

Laura Joszt, MA; and Mary Caffrey



MESA

RUBEN MESA, MD, FACP, president and executive director, Atrium Health Wake Forest Baptist Comprehensive Cancer Center and Atrium Health Levine Cancer Center.

MESA: Mometinib was one of the first therapies approved with a phase 3 registrational study (NCT04173494) that had symptomatic improvement

as the primary end point, with other important evidence of clinical benefit really as important, a kind of secondary end point, such as improvement in anemia and splenomegaly....There are data, both from the front line and the second line, demonstrating improvement in the symptomatic burden these patients face, as well as improvement in spleen size and in anemia.

In the end, patients really can have 2 concrete benefits from a therapy. They can either live longer, they can live better, or both.... In this study, again using patient-reported outcomes, we're able to hear directly from patients the benefits that they experienced. Now, indeed, we've done threshold work [with] patient-reported outcomes; the patient is really the judge and jury. What is symptomatic enough to benefit from therapy, to be on therapy, is very much assessed through the lens of the individual. ♦



MARY CAFFREY, JULIA BONAVITACOLA, SKYLAR JEREMIAS, JARED KALTWASSER, CAMERON SANTORO, AND PEARL STEINZOR.

FDA ACTIONS

FDA Approves First Subcutaneous Nivolumab Injection in Most Solid Tumors

THE FDA HAS APPROVED nivolumab and hyaluronidase-nvhy (Opdivo Qvantig) for subcutaneous injection across approved nivolumab (Opdivo) indications for adult, solid tumors as monotherapy, monotherapy maintenance following completion of nivolumab plus ipilimumab (Yervoy) combination therapy, or in combination with chemotherapy or cabozantinib (Cabometyx)

This makes nivolumab and hyaluronidase-nvhy the first subcutaneous PD-1 inhibitor for adult patients with solid tumor nivolumab indications.¹

“We are pleased Opdivo Qvantig, which is coformulated with our Enhance drug delivery technology, is now FDA approved as the first and only subcutaneously administered PD-1 inhibitor in the US,” Helen Torley, MBChB, MRCP, president and chief executive officer of Halozyme, maker of Enhance, said in a news release.² “This approval represents our ninth coformulated product and is yet another example of how Halozyme’s innovative Enhance technology is enabling greater flexibility and optionality for patients.”



TORLEY

“We are pleased Opdivo Qvantig, which is coformulated with our Enhance drug delivery technology, is now FDA approved as the first and only subcutaneously administered PD-1 inhibitor in the US. This approval represents our ninth coformulated product and is yet another example of how Halozyme’s innovative Enhance technology is enabling greater flexibility and optionality for patients.”

—Helen Torley, MBChB, MRCP,
President and CEO,
Halozyme

The December 27, 2024, approval covers indications for renal cell carcinoma (RCC), melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, urothelial carcinoma, colorectal cancer, hepatocellular carcinoma, esophageal carcinoma, gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma.¹ However, nivolumab and hyaluronidase-nvhy is not indicated in combination with intravenous ipilimumab.

The approval is based on findings from the phase 3 CheckMate-67T trial (NCT04810078), a randomized, open-label, noninferiority study evaluating its efficacy and pharmacokinetics compared with intravenous (IV) nivolumab in adult patients with advanced or metastatic clear cell RCC previously treated with systemic therapy.

Patients were randomly assigned to receive either subcutaneous nivolumab, administered as a flat dose of 1200 mg coformulated with 20,000 units of hyaluronidase every 4 weeks, or IV nivolumab at 3 mg/kg every 2 weeks, following dosing guidelines in place at the start of the study. Treatment was continued until one of the following occurred: disease progression, unacceptable toxicity, withdrawal of consent, completion of 2 years of treatment, or death.³

The trial demonstrated noninferiority for the co-primary end points of time-averaged concentration over 28 days and minimum concentration at steady state with geometric mean ratios of 2.10 (90% CI, 2.00-2.20) and 1.77 (90% CI, 1.63-1.93), respectively.¹ Additionally, a key powered secondary end point showed an overall response rate of 24% (95% CI, 19-30) in the nivolumab and hyaluronidase-nvhy arm, compared with 18% (95% CI, 14-24) in the IV nivolumab arm, confirming comparable efficacy.

The safety profile was consistent with that of IV nivolumab. Serious adverse reactions occurred in 28% of patients, with pleural effusion, pneumonitis, hyperglycemia, hyperkalemia, hemorrhage, and diarrhea reported in over 1% of patients.

Common adverse reactions ($\geq 10\%$ of patients) included musculoskeletal pain (31%), fatigue (20%), pruritus (16%), rash (15%), arthralgia (12%), and cough (11%). Fatal adverse reactions were reported in 3 patients (1.2%), attributed to myocarditis, myositis, and colitis complications. Adverse reactions led to treatment discontinuation in 10% of patients.

The recommended dosing for subcutaneous nivolumab varies by indication: 600 mg of nivolumab with 10,000 units of hyaluronidase every 2 weeks, 900 mg of nivolumab with 15,000 units of hyaluronidase every 3 weeks, or 1200 mg of nivolumab with 20,000 units of hyaluronidase every 4 weeks. Treatment continues until disease progression, unacceptable toxicity, or as specified in the prescribing information. ♦

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Tislelizumab Is Approved as First-Line Therapy for HER2– Gastric Cancers

THE FDA HAS APPROVED tislelizumab-jsgr (Tevimbra; BeiGene) in combination with platinum and fluoropyrimidine-based chemotherapy as a first-line treatment for unresectable or metastatic HER2-negative (HER–) gastric or gastroesophageal junction adenocarcinoma (G/GEJ) in adults whose tumors express PD-L1.¹

The approval follows its initial approval in March 2024, when tislelizumab was approved as a monotherapy for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-L1 inhibitor.² BeiGene has also submitted a biologics license application for the use of tislelizumab as a first-line treatment of adult patients with locally advanced unresectable or metastatic ESCC.

“This is the second US approval for [tislelizumab] this year, underscoring its potential to address critical needs in oncology,” Mark Lanasa, MD, PhD, senior vice president and chief medical officer for solid tumors at BeiGene, said in a news release.¹ “We remain deeply grateful to the patients, clinicians, and researchers whose commitment and courage have made this progress possible—and we look forward to building on this momentum in 2025.”



LANASA

The FDA based its decision on the results of the global, randomized, double-blind, placebo-controlled phase 3 RATIONALE-305 study (NCT03777657), which evaluated the efficacy and safety of tislelizumab in combination with chemotherapy as a first-line treatment for adults with advanced, unresectable, or metastatic G/GEJ cancers.¹

The trial enrolled 997 patients who were randomly assigned to receive either tislelizumab with investigator-selected chemotherapy or placebo with chemotherapy. The study met its primary end point, demonstrating a statistically significant and clinically meaningful improvement in overall survival (OS).

Patients treated with tislelizumab and chemotherapy achieved a median OS of 15.0 months compared with 12.9 months in the placebo group, representing an approximate 20% reduction in the risk of death (HR, 0.80; 95% CI, 0.70-0.92; $P = .0011$). Safety data pooled from 1972 patients across multiple studies revealed that common grade 3 or 4 adverse effects when tislelizumab was combined with chemotherapy included neutropenia, thrombocytopenia, anemia, fatigue, rash, pneumonia, pneumonitis, hypokalemia, hyponatremia, decreased appetite, hepatitis, and elevated liver enzymes. The findings highlighted tislelizumab's potential as a valuable first-line treatment option, providing significant survival benefits for patients with advanced G/GEJ cancers while maintaining a manageable safety profile.

“This is the second US approval for [tislelizumab] this year, underscoring its potential to address critical needs in oncology. We remain deeply grateful to the patients, clinicians, and researchers whose commitment and courage have made this progress possible—and we look forward to building on this momentum in 2025.”

—Mark Lanasa, MD, PhD,
Senior vice president and chief medical officer, Solid Tumors
BeiGene

Additionally, the National Comprehensive Cancer Network updated its guidelines for hepatocellular carcinoma (HCC) in 2024 to add tislelizumab as a category 1 other recommended regimen.³

Gastric cancer is the fifth most common cancer globally and ranks fifth in cancer-related deaths, with nearly 1 million new cases and 660,000 deaths reported in 2022.¹ In the US, approximately 27,000 new cases and 11,000 deaths were estimated in 2024, with a 5-year survival rate of 36%. GEJ cancer, which occurs where the esophagus meets the stomach beneath the diaphragm, represents a distinct and challenging subset of these cancers.

According to results of a study published in *Annals of Surgery*, patients with GEJ cancer have worse disease-specific survival and a higher recurrence rate than those with gastric cancer, with hematogenous recurrence being more common in GEJ cancer (60.1% vs 31.4%) and peritoneal recurrence more frequent in gastric cancer (52.9% vs 12.5%).⁴ Together, esophageal and gastric cancers account for 1.6 million new cases and 1.3 million deaths annually. GEJ cancer incidence has risen significantly, with a 2.5-fold increase in 2 decades, and noncardia gastric adenocarcinoma is increasing in younger individuals. Surgery remains central to treatment, but perioperative therapies play a key role in advanced cases. ♦

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FDA Approves Encorafenib With Cetuximab and mFOLFOX6 for Metastatic CRC

THE TREATMENT OF patients with metastatic colorectal cancer (mCRC) with a *BRAF*V600E mutation has been updated with the FDA's approval of encorafenib (Braftovi; Array BioPharma Inc) with cetuximab and the modified FOLFOX-6 (mFOLFOX6) chemotherapy regimen.¹ This combination received accelerated approval on December 20, 2024.

CRC is the second most common cause of cancer deaths in men and women combined,² with mCRC occurring in approximately 20% of patients with stage IV disease.³ Approximately 5% to 9% of all patients with CRC have *BRAF*V600E mutation,⁴ and prior to this approval they could be treated with encorafenib in combination with either cetuximab (Erbix) or panitumumab (Vectibix). This approval for mCRC adds mFOLFOX6 (leucovorin calcium [folinic acid], fluorouracil, and oxaliplatin)⁵ to the combination for these patients.

The approval was based on results of the phase 3 BREAKWATER trial (NCT04607421), which evaluated encorafenib plus cetuximab taken alone or together with standard chemotherapy to assess its efficacy in patients with mCRC with the *BRAF*V600E mutation.⁶ The trial was active-controlled, open-label, and multicenter. None of the participants could have had treatment for mCRC with the *BRAF*V600E mutation prior to the study.¹

Patients were eligible if they were 16 years or older, had confirmed stage IV CRC with a *BRAF*V600E mutation, had prior systemic treatment in a metastatic setting, had adequate organ function, had measurable disease, and had an ECOG status of 0 or 1. Patients who had tumors that were locally confirmed, had active bacterial or viral infections within 2 weeks of treatment, or had symptomatic brain metastases were excluded from the study.⁶

All participants were split into 3 groups, where they received either encorafenib plus cetuximab, encorafenib plus cetuximab with chemotherapy, or chemotherapy alone. Encorafenib was taken orally once per day in both groups that received the medication, with cetuximab received every 2 weeks. mFOLFOX6 and FOLFOXIRI (folinic acid, 5-fluorouracil, oxaliplatin, and irinotecan) were received every 2 weeks in the chemotherapy groups, whereas CAPOX (capecitabine [Xeloda] and oxaliplatin) was given every 3 weeks to those in the chemotherapy group. Disease progression, unacceptable toxicity, loss to follow-up, consent withdrawal, or death were reasons given for stopping treatment.

Objective response rate (ORR) was the trial's primary outcome. Investigators assessed efficacy in the first 110 patients randomly assigned to each arm and measured it by blinded review. Patients in the encorafenib with cetuximab and mFOLFOX6 arm had an ORR of 61% (95% CI, 52%-70%) compared with the control arm with an ORR of 40% (95% CI, 31%-49%). The duration of response was a median of 13.9 months (95% CI, 8.5-not estimable) in patients in the treatment arm compared with 11.1 months (95% CI, 6.7-12.7) in the control arm. The BREAKWATER trial is ongoing, and final calculations of progression-free survival and overall survival have yet to be formally assessed.

Adverse effects (AEs) included nausea, rash, fatigue, peripheral neuropathy, vomiting, abdominal pain, decreased appetite, pyrexia, and hemorrhage, all of which were reported in 25% or more of patients. The most common grade 3 or 4 AEs were increased lipase and decreased neutrophil count, both of which were reported in 20% or more patients. ♦

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Ensartinib Receives FDA Approval for ALK-Positive Locally Advanced or Metastatic NSCLC

ENSARTINIB (ENSACOVE) HAS RECEIVED FDA approval for use in treating adult patients with anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC), offering a new option that has led to improved progression-free survival (PFS).¹

Manufactured by Xcovery Holdings Inc and Betta Pharmaceuticals, ensartinib's new drug application was accepted by the FDA in March 2024.² The approval is based on results from eXalt3 (NCT02767804), a phase 3 randomized study that compared ensartinib with crizotinib in patients with ALK-positive NSCLC.³ Participants could not have received prior treatment with an ALK inhibitor.

A total of 290 patients were randomly assigned to receive either 225 mg of ensartinib once daily or 225 mg of crizotinib twice daily. PFS was the primary outcome, and overall survival (OS) was the main secondary outcome.¹

Patients taking ensartinib had significant improvements in PFS compared with those taking crizotinib (HR, 0.56; 95% CI, 0.4-0.79; $P = .0007$).¹ Ensartinib also had a statistically significantly longer median PFS than crizotinib (25.8 months vs 12.7 months).³ No statistically significant difference was reported for OS (HR, 0.88; 95% CI, 0.63-1.23; $P = .457$).¹

Adverse events (AEs) associated with ensartinib occurred in at least 10% of the patient population.³ Common AEs were mainly grade 2 or less, and included rash, elevated transaminase levels, pruritus, nausea, constipation, edema, anemia, vomiting, decreased appetite, and increases to blood alkaline phosphatase, blood creatinine, and γ -glutamyl transferase. Grade 3 rash was reported in 11.2% of patients (16 of 143) and was managed by withholding and reducing the dose.

The FDA recommended dose for ensartinib dosage is 225 mg orally once daily, either with or without food, until disease progression halts or unacceptable toxicity is reached.¹

Crizotinib is a first-generation ALK inhibitor and the first ALK inhibitor for patients with NSCLC.⁴ Second-generation ALK inhibitors include ceritinib, alectinib (Alecensa), brigatinib (Alunbrig), and ensartinib; lorlatinib (Lorbrena) is considered third generation. Both second- and third-generation ALK inhibitors are more potent than crizotinib and often are associated with higher frequency of ALK resistance mutations.⁵

The cost of ensartinib based on insurance coverage is not yet known. However, investigators in a study that analyzed a Chinese health care system found that ensartinib demonstrated cost-effectiveness compared with crizotinib.⁶ Additionally, the data showed ensartinib had reduced costs compared with ceritinib and brigatinib. Decreased total costs were also seen with ensartinib compared with lorlatinib and alectinib.



SELVAGGI

In an FDA news release, Giovanni Selvaggi, MD, chief medical officer of Xcovery, described ensartinib as a “novel and distinct first-line therapeutic option to [patients with] ALK-positive NSCLC.”² This approval offers patients with ALK-positive NSCLC a new treatment option, enabling health care providers to personalize treatment plans more effectively. ♦

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MANAGED CARE UPDATES

Subcutaneous Isatuximab Meets Primary End Points in Phase 3 Study for MM

STUDY RESULTS SHOW that a subcutaneous (SC) formulation of isatuximab (Sarclisa; Sanofi) is just as effective as the intravenous (IV) version of the drug in treating multiple myeloma, which could pave the way for an approval that would remove a major advantage for a competitor.¹

In topline results announced on January 9, 2025, Sanofi officials said the SC version of the anti-CD38 monoclonal antibody met co-primary end points in the phase 3 IRAKLIA study (NCT05405166), demonstrating noninferiority compared with IV isatuximab.¹ According to the statement, IRAKLIA is the first global phase 3 study to evaluate SC administration of a cancer therapy via an on-body delivery system (OBDS). The FDA has approved such systems for other treatments, which are designed to save time, allow freedom of movement during administration, and improve quality of life.

“The consistent overall response rate and comparable efficacy and safety profile observed in the IRAKLIA study for subcutaneous [isatuximab] represent an exciting advancement, offering insight into a potential new administration option for patients,” principal investigator Sikander Ailawadhi, MD, professor of medicine, Division of Hematology/Oncology at Mayo Clinic Florida, said in the statement. The results “support the potential of an on-body delivery system to help ease the delivery of a new formulation without impacting patient outcomes.”¹

SC administration has gained ground over IV administration of cancer therapies over the past decade because of patient convenience, lower cost, and reduced risk of infection. Another anti-CD38 monoclonal antibody, daratumumab (Darzalex; Johnson & Johnson), is already available in an SC formulation.²

Isatuximab binds to a specific epitope on the CD38 receptor on myeloma cells, producing a distinct antitumor response. It works through multiple pathways, including direct apoptosis, crosslinking of CD38 and CD16, and sensitizing T cells against CD38-positive cells. Daratumumab has some mechanisms of action similar to those of isatuximab but not

direct apoptosis.³

Both isatuximab and daratumumab have been approved in combination with bortezomib, lenalidomide, and dexamethasone for patients with newly diagnosed multiple myeloma.⁴

In the IRAKLIA study, investigators used an OBDS developed by Enable Injections, which gained approval for an on-body injector in October 2023 to deliver pegcetacoplan (Empaveli) for paroxysmal nocturnal hemoglobinuria. The product, called Enfuse, rapidly gained acceptance among patients who were currently taking pegcetacoplan and was prescribed to 90% of new users

“The consistent overall response rate and comparable efficacy and safety profile observed in the IRAKLIA study for subcutaneous [isatuximab] represent an exciting advancement, offering insight into a potential new administration option for patients. [The results] support the potential of an on-body delivery system to help ease the delivery of a new formulation without impacting patient outcomes.”

—Sikander Ailawadhi, MD,
professor of medicine, Division of Hematology/Oncology,
Mayo Clinic Florida

by February 2024.⁵

In the trial involving patients with relapsed or refractory multiple myeloma, isatuximab was administered at a fixed SC dose via the Enfuse OBDS in combination with pomalidomide and dexamethasone. Sanofi officials said the study met co–primary end points of noninferior objective response rate and observed concentration before dosing at a steady state, compared with IV isatuximab at a weight-based dose in combination with pomalidomide and dexamethasone.¹

Key secondary end points, which included very good partial response and incidence rate of infusion reactions, were also achieved. Full results of the ongoing study will be presented at a future medical meeting. Additional studies evaluating SC formulations of isatuximab across different combinations and lines of therapy are ongoing. According to the statement, regulatory submissions in the United States and Europe are anticipated in the first half of this year.¹ ♦

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Limited Benefits of ctDNA Testing in Colorectal Cancer Surveillance, Study Finds

AMONG A COHORT OF patients with stage II to IV colorectal cancer (CRC) who underwent curative-intent resection, the addition of serial circulating tumor DNA (ctDNA) testing provided limited clinical benefit.¹ The

retrospective, case-cohort study is published in *JAMA Network Open*.¹

“Our findings suggest that there may be a more limited role for serial ctDNA testing in the surveillance setting when using a more frequent imaging schedule, as recommended by the current National Comprehensive Cancer Network guidelines,” the study researchers wrote. “More robust prospective studies, including cost-effectiveness studies, are needed to determine the value of serial ctDNA testing in the surveillance setting and to justify the incorporation of such assays in routine clinical practice.”

ctDNA has been identified as a prognostic biomarker that can help define the risk of recurrence after curative-intent surgery, as well as a predictive tool to guide treatment decisions in adjuvant and metastatic settings.²

In this study, the researchers aimed to examine the benefits of adding serial ctDNA assays for potential curative outcomes in patients with resected CRC.¹ The cohort included patients who underwent ctDNA testing between September 20, 2019, and April 3, 2024. Surveillance protocols involved serial ctDNA testing every 3 months for 2 years, then every 6 months for the next 3 years. Reflex imaging, triggered by positive ctDNA results, was performed every 3 months until recurrence was confirmed. Recurrence was defined by positive imaging or ctDNA assays. The study population was divided into 4 cohorts based on ctDNA

“Our findings suggest that there may be a more limited role for serial ctDNA testing in the surveillance setting when using a more frequent imaging schedule, as recommended by the current National Comprehensive Cancer Network guidelines. More robust prospective studies, including cost-effectiveness studies, are needed to determine the value of serial ctDNA testing in the surveillance setting and to justify the incorporation of such assays in routine clinical practice.”

—Study authors

and imaging results, with additional stratification for those with reflex imaging.

The primary outcome was the proportion of patients benefiting from ctDNA testing, defined as cases where ctDNA positivity led to early imaging-based recurrence detection and subsequent curative-intent interventions without evidence of recurrence at data cutoff.

A total of 184 patients were included, of which 45 had recurrent disease, 11 had recurrence with concurrently positive ctDNA and imaging findings, 14 had recurrence by imaging with a negative ctDNA assay, and 20 had a positive ctDNA recurrence with negative imaging studies.

Among the 45 patients evaluated, 20 experienced ctDNA positivity with negative imaging at the time of the first positive ctDNA result. Of these, 6 patients underwent reflex imaging, which confirmed recurrence, whereas the remaining 14 continued with serial imaging and ctDNA monitoring. Among the latter group, 10 patients were later diagnosed with recurrent disease, 3 experienced spontaneous ctDNA clearance without recurrence, and 1 remained imaging negative for 7 months post ctDNA positivity before being lost to follow-up. Overall, 11 of the 20 patients with ctDNA-detected recurrence without concurrent imaging findings underwent metastasectomy, but only 3 remained disease free at the data cutoff in April 2024. This accounted for just 1.6% of the total surveilled population, highlighting the limited clinical benefit of ctDNA testing in this context.

This study has several limitations. Its retrospective design restricted the interpretation of findings, and the follow-up duration varied, with some patients only partially completing the surveillance schedule. This contributed to a low observed prevalence of disease recurrence. The small sample size may have underestimated the clinical impact of serial ctDNA testing. Additionally, patients without recurrence had not yet completed a full 5-year follow-up, potentially leading to an overestimation of clinical benefit.

Despite these limitations, the researchers believe the study finds limited clinical benefit of adding ctDNA assays to standard-of-care surveillance for

patients with stage II to IV CRC.

“Future prospective trials are needed to evaluate whether the addition of ctDNA to surveillance improves relevant clinical outcomes, including patient-reported outcomes, over the standard of care and whether the frequency of testing is worth the cost and psychological impact on patients,” the researchers wrote. ♦

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Impact of Sexual Counseling on Women With Breast Cancer

BREAST CANCER and its treatments can significantly impact a woman's sexual function and self-efficacy, leading to decreased sexual well-being.¹ A recent study assessed the effectiveness of sexual counseling and education based on self-efficacy theory in enhancing sexual function in women with breast cancer, focusing on the outcomes of counseling interventions in improving various domains of sexual function, offering promising insights

for noninvasive, cost-effective approaches to support survivors' sexual health. Findings from the randomized controlled trial were published in *BMC Women's Health*.¹

“In analyzing the research hypotheses, both within- and between-group comparisons indicated that the intervention led to an increase in overall sexual function scores and sexual desire, lubrication, orgasm, and sexual satisfaction domains during the intervention period compared to preintervention, extending to the follow-up period in the intervention group which meant that the sexual counseling and education based on self-efficacy theory was effective on overall sexual function and the mentioned domains,” wrote the researchers of the study.

Survivors of breast cancer represent more than 40% of all cancer survivors, and approximately 50% have reported some type of sexual difficulty and 45% have reported sexual pain, according to one study.²

The study employed a pretest, posttest, and follow-up design to measure changes in sexual function across 3 time points. The study population consisted of 50 married women diagnosed with breast cancer, aged 18 to 50 years, who had undergone at least 1 lumpectomy and experienced sexual dysfunction in at least 1 domain, as indicated by a score below 3.9 on the Female Sexual Function Index. Participants were selected from the hematology departments of hospitals in Bushehr, Iran, between 2023 and 2024. Inclusion criteria required participants to be at least 3 months post chemotherapy or radiotherapy, and exclusion criteria included current psychiatric treatment, pregnancy, or other conditions interfering with sexual function.

Participants were randomly assigned to either an intervention or control

SPOTLIGHT

AI's Role in Oncology Aims to Support, Not Replace, Health Providers

Interview by Maggie L. Shaw



OSTERMAN

TRAVIS OSTERMAN, DO, MS, FAMIA, FASCO, associate vice president for research informatics; director, cancer clinical informatics, Vanderbilt University Medical Center.

ALTHOUGH ARTIFICIAL INTELLIGENCE (AI) offers great promise in oncology, some professionals express concerns over the loss of human connection. In this interview, Travis Osterman, DO, MS, FAMIA, FASCO, associate vice president for research informatics and director of cancer clinical informatics, Vanderbilt University Medical Center (VUMC), discusses the smart use of AI in cancer care and how health care providers and the tech world can collaborate to build trust in AI-driven care without compromising the patient-provider relationship. This interview took place during an Institute for Value-Based Medicine event presented with *The American Journal of Managed Care (AJMC)*.

This transcript has been lightly edited for clarity.

AJMC: What are some of the most impactful applications of AI you've seen in oncology?

OSTERMAN: A big trend, not just in oncology, but nationwide is something called ambient scribe. Ambient scribe is a technology that's being implemented by a number of companies and certainly investigated by researchers nationwide and probably worldwide.

The concept goes like this: What if we had a microphone in the system in the room where an oncologist is talking to the patient, and the oncologist could turn and actually talk to the patient and have that natural conversation? The microphone is smart enough to understand who is saying what, can capture that conversation, and can then draft what would be a note in the style that you normally write your clinical notes. That way, the oncologist isn't tied to the computer. They're able to have a more humanistic interaction with their patient while still getting their work done.

For me, I think that's probably one of the biggest opportunities. You'll hear a lot of things in the treatment and diagnosis space, and I think there are really great opportunities there. But the opportunity, ironically, for AI to bring a more humanistic touch to how we practice oncology, I think, is probably one of the biggest opportunities that we have.

AJMC: How can the health care and tech worlds best collaborate to build trust in AI-driven cancer care?

OSTERMAN: I'm a strong proponent that none of these decisions should be made in a vacuum. We need all the stakeholders at the table. Importantly, that includes patients and our communities. Sometimes researchers ask too late whether we *should* when they're trying to figure

group, with each consisting of 25 women. The intervention group received 2 educational sessions and 3 counseling sessions over a 4-week period while the

“Health care providers interacting with breast cancer patients in various stages of the disease, including diagnosis, treatment, and posttreatment rehabilitation, can use this method as an easy, cost-effective, and practical approach to enhance the sexual quality of life of breast cancer patients alongside other medical interventions.”

—Study authors

control group received no intervention.

The results revealed no significant differences in demographic variables, including age, time since diagnosis, or the number of children, between the intervention and control groups ($P > .05$). Prior to the intervention, the mean (SD) total sexual function scores for the intervention and control groups were 16.50 (8.30) and 16.04 (8.24), respectively, with no significant differences observed ($P > .05$).

Changes in overall sexual function, as well as in the arousal, orgasm,

lubrication, and satisfaction domains, from pretest to posttest and pretest to follow-up showed an increase in the intervention group and a decrease in the control group, with statistically significant differences between the 2 groups ($P < .05$). However, the average changes from posttest to follow-up were not statistically significant between the groups.

This study had several limitations. One key limitation was the absence of spouses' participation, which could have impacted the results, as sexual function is influenced by both partners. Additionally, the sample was limited to a specific geographical region with a small number of participants, and the voluntary, goal-based sampling approach may have limited the generalizability of the results.

Despite these limitations, the researchers believe the study highlights the clinical importance of strengthening self-efficacy beliefs related to sexual health, which can boost women's confidence and skills in overcoming sexual challenges, ultimately improving their sexual well-being.

“Health care providers interacting with breast cancer patients in various stages of the disease, including diagnosis, treatment, and posttreatment rehabilitation, can use this method as an easy, cost-effective, and practical approach to enhance the sexual quality of life of breast cancer patients alongside other medical interventions,” wrote the researchers. ♦

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out whether we *can*, and they're pushing the limits of technology forward. But we need to ask those questions very early on.

What is the acceptance rate of having these things recorded in the room? Our patients—will they feel comfortable having the same conversations, for instance, in a room with the ambient scribe? How will they react to these new data points that are intended specifically for them in terms of predictive analytics and these new algorithms? I think these are things that are evolving and that we need to figure out.

On the project where we're predicting the outcomes and toxicities to immunotherapy,¹ one of the biggest challenges that I continue to wrestle with is: What's the best way to display these data so that patients and their clinicians can have a more informed conversation? The last thing I want to do is make a cold recommendation on treatment, yes or no. What I want to do is provide the information in a way that the oncologist and patients can look at the screen together, understand that risk, understand that benefit, and then make a precise decision that takes into account that patient's value system, the kind of life they want to live, and their risk tolerance, with all the information necessary. I think sometimes we jump to AI giving solutions, but I hope the first step is AI surfacing the right information in a way that we can all understand so we can make better decisions.

Everyone likes to do the studies of AI vs radiologists or AI vs pathologists. I don't think we're even close to any of those things. Now, are we close to AI being a sidekick? Are we close to it being the medical assistant or the trusted nurse or the resident or fellow alongside a seasoned attending? We will get closer, and we'll get closer faster, I think, than many of us think, but I don't think it's going to replace health care delivery anytime soon.

AJMC: How do care teams incorporate clinical informatics data into their treatment plans?

OSTERMAN: I really like the way Monica Bertagnolli, MD, who's our director of the NIH [National Institutes of Health]. She was the ASCO

[American Society of Clinical Oncology] president in 2019, and her presidential theme in 2019 for our professional society was “Learning From Every Patient,” and that's always really stuck with me. We should learn from every patient encounter that we have as clinicians. I think that rings true. You want to take that experience and learn. It's a medical practice. I'm trying to get better every day, and I hope I can deliver better-quality care every single day in my practice.

But we should be doing that not just at the individual clinician level. We need to do that at the entire medical practice level, at the system level, and to do that, we need to put systems in place to leverage all these data to try to move the entire field forward. I think we owe that to our patients.

We work very, very closely with our privacy office and compliance office here [at VUMC], so when you're talking about training these models, you need to be in a HIPAA [Health Insurance Portability and Accountability Act]–compliant environment. That's a combination of both the technology and the contracts to make sure we have agreements in place between all the entities involved. The project that I'm part of, with GE HealthCare—this is using entirely deidentified data.

We're much more interested in the outcomes, and there's not really a reason to have individually identified information in that data set. So we've followed standard deidentification protocols and standards to do that. This is something that we're really lucky [to have] at Vanderbilt. We have experts like Brad Malin, PhD, here, who's one of my colleagues in the Department of Biomedical Informatics and an internationally known researcher in the privacy space. Our chief privacy officer, Sandra Hornsby, MEd, CHPC, is an incredible woman to work with and incredibly talented in the privacy space. So we are super well supported to be able to keep these concerns at the forethought of all the work we do. ♦

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CLINICAL UPDATES

Ruxolitinib Combinations in MPNs: Updates From ASH

FOLLOWING ITS APPROVAL IN 2011 for myelofibrosis (MF),¹ ruxolitinib (Jakafi; Incyte) became the backbone of treatment for MF and later for polycythemia vera, which are 2 of the 3 common myeloproliferative neoplasms (MPNs).

However, although ruxolitinib improves survival outcomes and quality of life, some patients may not respond to therapy, whereas others may stop due to genetic mutations, disease progression, or other factors. For years, investigators have been studying the Janus kinase (JAK) inhibitor in combination with other drugs in first-line treatment and refractory disease.² Abstracts and oral presentations at the recent 66th American Society of Hematology (ASH) Annual Meeting and Exposition, held December 7 to 10, 2024, in San Diego, California, offered updates on several combinations in the pipeline.

MANIFEST-2

Previous results from this phase 3 study (NCT04603495) of pelabresib, a selective BET inhibitor, with ruxolitinib show that it met its primary end point. In patients with MF not treated with a JAK inhibitor, a statistically significantly higher proportion showed at least a 35% reduction in spleen volume from baseline at week 24 with the combination vs ruxolitinib and placebo.³ Results presented at ASH showed that those results were maintained after a median follow-up of 72 weeks, with a 48-week response rate of 57.0% for the combination vs 37.5% for ruxolitinib and placebo. An improvement in the Myelofibrosis Symptom Assessment Form total symptom score (TSS) by at least 50% was seen in 45.3% of patients receiving the combination vs 39.4% in the placebo group.⁴

Bomedemstat

An abstract at ASH reported on an ongoing phase 2 study (NCT05569538) involving bomedemstat combined with ruxolitinib in patients with advanced MF.⁵ Bomedemstat is an irreversible inhibitor of LSD1, which plays a role in gene regulation; blocking this enzyme alters cell differentiation and growth. In August 2024, Merck announced the second phase 3 trial of bomedemstat in another MPN: essential thrombocythemia.⁶

The abstract authors noted that approximately 50% of patients with MF stop ruxolitinib after 3 years, mostly due to disease progression or cytopenia; the median OS after discontinuation is 14 months.⁵ LSD1, they write, is “critical for self-renewal” of cancerous stem cells and has shown promise as a single agent. This study reported on 2 cohorts: Cohort A had a suboptimal response to ruxolitinib, and cohort B patients had MF and were treatment naïve. Patients in cohort A remained on the entry dose of ruxolitinib, whereas cohort B started 10 mg twice per day; all patients received a starting dose of 0.4 mg/kg/day of bomedemstat. Dose adjustments were permitted every 4 weeks to achieve an optimal platelet count, and downward titrations were done at any time for safety reasons. After a median of 61.7 weeks, in 40 evaluable patients at week 24, 11 patients had at least a 50% improvement in TSS (cohort A, 25.9%; cohort B, 30.7%), 17.5% had at least a 35% spleen volume reduction (cohort A, 7.4%; cohort B, 38.5%), and 50% had stable or improved hemoglobin (cohort A, 51.9%; cohort B, 46.3%). There were no safety signals or deaths related to the drug, according to the authors.⁵

RESTORE

Data from the ongoing phase 2 RESTORE trial (NCT05037760), involving elritercept with and without ruxolitinib, continued to demonstrate that the investigational therapy showed benefits in spleen volume reduction and improved TSS and that it “can potentially ameliorate ineffective

hematopoiesis and address cytopenias” in patients with MF, according to a statement from Keros Therapeutics, Inc, which is developing the drug.⁷

Keros describes elritercept, which is also being studied in myelodysplastic syndromes, as “an engineered ligand trap [featuring] a modified ligand-binding domain of the [transforming growth factor]- β receptor known as activin receptor type 2A that is fused to the portion of the human antibody known as the Fc domain.” A recent study in *Blood* stated that in preclinical studies, a research form of elritercept increased red blood cells and platelet production in healthy and diseased mouse models, supporting additional studies.⁸

According to Keros, this ongoing, open-label, 2-part trial is evaluating elritercept administered with or without ruxolitinib in patients with MF who have anemia and were either already receiving, had experienced treatment failure with, or were ineligible for ruxolitinib at baseline. Study authors presented safety data for 73 patients who received at least 1 dose of elritercept as of the August 30, 2024, data cutoff date, as well as efficacy data for evaluable patients.^{7,9} Data presented included evaluations of markers of hematopoiesis and anemia over 12 weeks, along with measurements of spleen volume and TSS scores over 24 weeks for dose levels 1 through 4, which ranged from 0.75 mg/kg to 5.0 mg/kg. A second part, the dose expansion portion, is now enrolling.

Increases in hemoglobin were seen in 82.8% of evaluable non-transfusion dependent patients in both arms over a 12-week period in the first 24 weeks, which Keros officials said suggested the potential of a new option to address anemia. Spleen volume was reduced in 40% of patients, with 3 having reductions of at least 35%. Five patients had a reduction of at least 50% in their TSS score: 3 in the monotherapy arm and 2 in the combination arm. There were 6 cases of treatment-emergent adverse events deemed unrelated to treatment; the most common adverse events were thrombocytopenia and diarrhea. ♦

Just before ASH 2024, Keros announced a licensing agreement with Takeda.¹⁰

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Efgartigimod Leads to Sustained Myasthenia Gravis Improvement

PATIENTS WITH GENERALIZED myasthenia gravis (gMG) and acetylcholine receptor (AChR) autoantibodies saw sustained improvement on efgartigimod (Vyvgart), according to a new post-hoc analysis.

Writing in the *Journal of Neurological Sciences*, corresponding author Sarah Dewilde, PhD, of the consultancy Services in Health Economics, and colleagues said data from the ADAPT clinical trial (NCT03669588) and its open-label extension (ADAPT+; NCT03770403) affirm the original study's findings regarding the safety and efficacy of the therapy.¹

"Results from our analysis indicate that improvements in strength and function are sustained over time in the gMG population and are consistent regardless of the definition of response, and despite the strict retreatment criteria applied in the ADAPT studies," they wrote.

Approximately 85% of people with gMG are positive for AChR autoantibodies. Conventional therapies for the disease include acetylcholinesterase inhibitors and broad-acting immunotherapies, the authors noted. Yet, in many patients, the clinical benefits of such therapies are limited, and adverse effects such as weight gain, arterial hypertension, infections, and

glucose intolerance have been reported.

"There consequently remains a significant unmet need for alternative treatments in gMG that are effective, rapidly acting, and well tolerated," they wrote.

Recently, new biologic therapies have begun to change the treatment landscape for people with gMG. Among them is efgartigimod, which targets the Fc receptor. The therapy has been approved by regulators in the US, Japan, and Europe, thanks to the positive results of the original ADAPT trial.² In that trial, the results of which were published in 2021, two-thirds (68%) of patients who were AChR antibody positive responded to the therapy in the first treatment cycle.² That trial defined a response as improving by at least 2 points on the MG Activities of Daily Living (MG-ADL) assessment and sustaining that improvement for at least 4 weeks. In the placebo group, the response rate was just 30%.

Patients from the original trial were eligible to continue in the single-arm, open-label extension follow-up study, dubbed ADAPT+.³ Although the original publication of the ADAPT+ results focused on safety and tolerability through 64 weeks of treatment, the authors said this new post-hoc analysis was designed to assess whether efgartigimod led to a sustained, clinically meaningful response.³

For this post-hoc analysis, the investigators defined response to treatment as a 5-point reduction on the Quantitative MG (QMG) assessment, or a 3-point improvement in the MG-ADL assessment, compared with baseline.

The investigators found that people in the ADAPT trial who received therapy had a substantially higher percentage of time in response both

SPOTLIGHT

Next-Gen Strategies for Resistance in *EGFR*-Mutated Lung Cancer

Interview by Maggie L. Shaw



SABARI

JOSHUA K. SABARI, MD, assistant professor of medicine, thoracic medical oncology, Perlmutter Cancer Center, NYU Langone Health.

DURING A RECENT Institute for Value-Based Medicine event presented by *The American Journal of Managed Care (AJMC)*, we spoke with Joshua K. Sabari, MD, about the approval of amivantamab plus lazertinib for newly diagnosed patients with non-small cell lung cancer (NSCLC). In this interview, Sabari looks ahead to potential uses that could help to overcome treatment resistance.

AJMC: What are some top ongoing challenges in treating NSCLC?

SABARI: What's interesting is that amivantamab seems to have broad activity, not [only] in the common *EGFR* mutations but [also] across all *EGFR* mutations, including exon 20 and the uncommon, or historically atypical—we now call them the PaC mutations—PaC helix mutations in this population. More broadly than *EGFR* muta-

tion-positive lung cancer, this is a therapy that is being looked at in other diseases and histologies, primarily colorectal cancers.... It's an exciting opportunity. It's the first frontline indication for amivantamab in combination with lazertinib—again, building on what is a standard of care, a third-generation *EGFR* [tyrosine kinase inhibitor].

Focusing specifically on *EGFR*, we've sort of plateaued in the sense of developing our fourth-generation inhibitors. We need to start thinking more broadly to encompass resistance. We know that *MET* amplification is common, occurring in 10% to 12% of patients. We know that C797S is also occurring [approximately] 8% to 10%, [which is] a point mutation in exon 20. We also know that we have such a broad range of heterogeneous alterations as resistance in the second-line setting [and beyond].

We need to better understand resistance mechanisms, particularly resistance mechanisms against amivantamab, the *EGFR*-*MET* bispecific. In understanding those resistance mechanisms, we'll then be able to develop and design our next-generation therapeutics. So, despite amivantamab and lazertinib being a phenomenal treatment option for patients in the frontline setting, I think we're going to build on that as well. So, [these are] exciting opportunities with *EGFR* and *MET* [antibody-drug conjugates], as well as *EGFR* and CD3 T-cell engagers in the *EGFR* population space.

One of the holy grails in the *EGFR*-mutant space has been the lack of immune response in this population, and...with amivantamab, especially with the Fc portion of the bispecific antibody, we're starting to see some immune activation. I think that's where the next generation of inhibitors are going to go. ♦

when using the QMG end point (44% vs 13%; $P = .0034$) and on the 3-point MG-ADL end point (59% vs 30%; $P = .010$) during weeks 0 through 20 of the ADAPT trial. For both end points, the investigators said the benefits were sustained throughout the ADAPT+ extension period.

Dewilde and colleagues noted that the higher response rates seen when using the MG-ADL assessment compared with the QMG assessment are consistent with other trials of gMG therapies.

“Instruments based on patient-reported outcomes, such as MG-ADL, are often subject to greater variability and data may consequently be noisy in comparison [with] the QMG end point, which is an objective measure based on clinical assessment,” they wrote.

However, they added that due to the objective, clinician-assessed nature of the QMG scores, the fact that the therapy significantly outperformed placebo is “particularly noteworthy.”

Dewilde and colleagues also wrote that their findings showed that efgartigimod had a sustained positive effect whether or not patients had received prior immune therapy, and regardless of the time since patients were diagnosed with the disease.

The authors noted that response rates fluctuated over time, and they added that assessments in ADAPT were performed weekly up to week 8 and then

biweekly, whereas ADAPT+ assessments were performed during the 4 weekly infusion visits of a treatment cycle and then only monthly. They said that the assessment schedule rendered the data capture “suboptimal.” Still, they said the overall percentages of patients responding to therapy was notable and impressive.

“Overall, the results of this analysis indicate that efgartigimod is an effective therapeutic option, demonstrating robust and sustained benefit in a broad patient population with gMG and [who are] AChR antibody positive,” they concluded. ♦

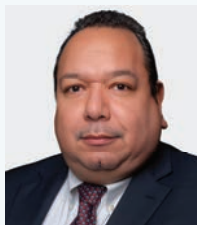
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SPOTLIGHT

Harnessing AI to Revolutionize Lung Cancer Care

Skylar Jeremias



SANTOS

EDGARDO S. SANTOS CASTILLERO, MD, FACP, FASCO, hematologist and oncologist, The Oncology Institute for Hope and Innovation.

ARTIFICIAL INTELLIGENCE is playing a growing role in advancing lung cancer care, particularly in diagnostics and treatment. Edgardo S. Santos Castillero, MD, FACP, FASCO, a hematologist and medical oncologist at The Oncology Institute of Hope and Innovation, highlighted artificial intelligence’s potential in analyzing imaging data, such as identifying irregularities in x-rays or computer tomography (CT) scans that may indicate malignancies, as well as detecting patterns of interstitial lung disease caused by medication or radiation.

Additionally, Santos said, artificial intelligence can predict driver mutations by analyzing biopsy images, potentially eliminating the need for molecular testing. While acknowledging artificial intelligence’s vast potential, Santos emphasized the importance of regulation to ensure its safe and ethical use in health care.

This transcript has been lightly edited for clarity.

AJMC: How are artificial intelligence and machine learning being used to advance lung cancer care, from diagnosis to treatment?

SANTOS: Well, that’s another hot topic right now: artificial intelligence. Artificial intelligence can be in any single aspect of our life, from our daily activities, finance, agriculture, banking, and also in health care. So, again, just talking about lung cancer, artificial intelligence will

have many utilities. The recent ones that I have learned about are in the imaging setting. Artificial intelligence collects data from thousands of images and can predict, for example, if an irregular x-ray or CT scan could tell that a patient may have a malignant disease ongoing and could perhaps alert the physician to either [follow it closely] or perform a biopsy.

Another example for when [artificial intelligence is] collecting thousands of images, there is a problem that we call in lung cancer “interstitial lung disease,” which basically is an inflammatory pattern. Today, there are different patterns of interstitial lung disease, and sometimes we have difficulty seeing it because of radiation oncology or inflammation in the lung field or because of the medication that the patient is taking. And this is very important, because it’s very tricky [to figure out] how we are going to handle this issue with our patient. So artificial intelligence is collecting these thousands of inflammatory processes in the lung that they can predict if this is secondary to the medication or secondary to radiation therapy, and that will help the clinician, again, to manage the patient.

Believe it or not, there is another technology in artificial intelligence collecting thousands and thousands of biopsies seen on a microscope and just by looking at the parent of the adenocarcinoma and how the cells look, the artificial intelligence can predict if the patient has a particular driver mutation. Amazing!

So, without doing molecular testing, and just by looking the pattern and the structure of the cells, [the artificial intelligence] can predict that.

You can see how, by collecting thousands of [pieces of] information, AI can help us in the future. And this is going to be the future. However, as you heard in the news, artificial intelligence must be regulated, because in the wrong hands it can hurt people. That’s another issue that is not for us. But certainly, [artificial intelligence] has a lot of potential that, as humans, we need to be savvy about how to handle it. And [we need to figure out] how to moderate, utilize, and legislate that kind of advancement in technology in general. ♦

Financial Navigation: Lessons From a Program in Practice

NATALIE DICKSON, MD, MMHC, FACP; AND SAMYUKTA MULLANGI, MD, MBA

CONTINUED FROM COVER

from a lack of data describing its extent. Study results showed almost three-fourths of patients reported experiencing serious financial hardship in the first year of diagnosis.³ In addition, patients with cancer are 2.5 times more likely to file for bankruptcy,⁴ and patients with cancer who go bankrupt are 80% more likely to die than patients who don't.⁵ The roots of financial navigation in cancer care trace back to the broader movement toward patient advocacy and holistic care in the late 20th century.⁶ Initially, financial assistance was often limited to charity care programs or one-off interventions through philanthropic organizations. However, the escalating costs of novel cancer therapies and the growing complexity of health insurance systems led to the need for a structured approach.

Over the years, financial navigation programs have become pivotal in mitigating these challenges⁷ by providing patients with tailored support to manage their financial responsibilities while accessing lifesaving treatments—inclusive but not limited to finding assistance for medical co-payments; handling nonmedical costs related to care such as transportation, lodging, and meals; managing employment; and navigating disability benefits.

Most comprehensive financial navigation programs, which equitably identify patients at risk and provide assistance proactively, are limited to larger health systems because of resource constraints.⁸ For example, a 2017 survey of community oncology practices found that less than half of practices had staffed a program to routinely provide patients with this service.⁹ Thus, this essay presents Tennessee Oncology's program as a model for other community oncology practices seeking to build or enhance their financial navigation services.

Tennessee Oncology's Program in Financial Navigation

At Tennessee Oncology, the financial navigation program is not just a nice-to-have benefit for our patients. It is deeply embedded into our strategy and clinical operations, and over time it has become a core component of our success in diverse communities across the state.

TRAINING. Our financial navigators undergo structured training through programs and certifications such as the Association of Cancer Care Centers Financial Advocacy Boot Camp as designated by CMS.¹⁰ In addition, they participate in video simulations with patients, proctored field experiences (30 days with a preceptor navigator), and graded role plays with scripting. We have internally developed training modules that familiarize our financial navigators with key health care concepts and our electronic medical record and practice management system. This structured approach allows for consistency, a cornerstone to achieving effectiveness.

STAFFING RATIOS. Different staff help patients with their medical expenses (inclusive of Part B drug spend) and the specialty pharmacy side (for Part D drug spend). The personnel who work to close gaps on the medical expense side are *navigators*; they almost always have a nursing background. The personnel within the specialty pharmacy are *advocates* and typically are pharmacy technicians operating under direct pharmacist oversight. In addition to slight variations in educational and training backgrounds, their scopes of work and staffing ratios are also slightly different. Tennessee Oncology's investment across the practice in this concept is reflected in the staffing ratios of navigators to patients. Each month, our nurse navigators each work with 250 to 300 patients; our financial navigators each work with 300 to 350 patients.

TECHNOLOGY. A hallmark of Tennessee Oncology's program is its strategic use of technology. Investments have been made in vendors that provide us with financial award availability and tracking software that captures financial data including income, credit scores, and propensity to pay. This information is fully integrated into our electronic medical record and practice management systems, including telemedicine to expand the reach of counselors across our 37 clinic sites and rural patient communities, and data analytics for performance and patient tracking.

DATA ANALYTICS. These tools, alongside a systematic approach toward data collection and gap analysis, enable navigators to personalize interventions and identify gaps in existing support mechanisms. For example, following the implementation of the validated Hunger Vital Sign¹¹ in 2022, analytics revealed that food insecurity was a critical issue for patients, with many choosing between paying for their groceries or paying the cost-sharing component of their cancer treatment and therefore forgoing necessary treatment.

PROGRAMMATIC EFFORTS. Data help us think creatively and proactively find solutions for our patients. Although our preference is to connect patients to existing community (local, regional, national) resources, such as the American Cancer Society, Meals on Wheels, Gilda's Club, and others, in this example, we uncovered a widespread patient need that was not being fully managed by existing programs. We then partnered with local food bank Second Harvest¹² to create a program in which food-insecure patients were provided with food boxes for an entire year. In an echo of Project Last Mile¹³—an initiative in which health care providers leveraged the Coca-Cola company's supply chain to expand access to HIV and malaria medicines across Africa—Second Harvest ships food boxes by using the courier system that Tennessee Oncology has set up to transport cancer medications to communities across the state.

SYSTEMATIC APPROACH WITH A HIGH FINANCIAL RETURN ON INVESTMENT. At our practice, every patient with out-of-pocket costs has an appointment with a financial counselor to discuss insurance coverage and benefits prior to the start of treatment. If patients are uninsured, navigators refer them to agencies that assist in screening for eligibility for Medicaid and Marketplace plans. We practice in a state that has not expanded Medicaid, and a significant proportion of our patients remain uninsured. Navigators first provide an estimate of patient responsibility; in fact, this is a core component of the Institute of Medicine's care management plan. They leverage a combination of foundation and grant programs, manufacturer co-pay card programs, manufacturer free-drug programs, and employment and disability benefits to help cover the gap between a patient's ability to pay after insurance coverage and total cost of care. Our analytics show that each financial navigator typically generates \$1 million to \$4 million in revenue annually to cover patient out-of-pocket costs, and additional millions in provided drugs for uninsured and underinsured patients. In fact, this revenue generated against the navigator's salary expense amounts to a stunning 22:1 for infusion drugs, and 85:1 for oral specialty drugs.

Of course, cancer is a long journey, and despite our navigators' best efforts, patients are not going to always find sources of funding every time they need it. Knowing this—and keeping with our practice's philosophy to do good *and* do well—we have a financial hardship policy to forgive unpaid patient balances on the medical benefit spend, and thus we are able to provide indigent care. We do not discriminate against patients who lack insurance, and we



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MULLANGI

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do not involve collections agencies over unpaid bills. This policy is the capstone of our entire financial navigation program, and it allows the financial navigation team to remain mission-oriented in their work with patients. Our goal is always to serve our patients first, and at the end of the day, restoring and maintaining patients' financial health is equally as important as their physical health.

The history of financial navigation in cancer care reflects an ongoing commitment to addressing the economic challenges faced by patients. Tennessee Oncology's program showcases how a comprehensive, integrated approach can mitigate financial toxicity, improve access to care, and enhance patient outcomes. By adopting similar strategies, other practices can contribute to a more equitable and compassionate oncology care landscape. As the field continues to evolve, financial navigation will undoubtedly remain a critical pillar in achieving health equity for all patients with cancer.

ABOUT THE AUTHORS

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TECHNOLOGY

Flatiron Health, DeepScribe Unveil Partnership to Provide Oncology-Specific Ambient AI

Mary Caffrey

DEEPSCRIBE, which has announced a string of partnerships for its ambient artificial intelligence (AI) technology, today entered into a relationship with Flatiron Health, which uses real-world evidence to provide point-of-care solutions for oncology providers.

According to a statement from Flatiron, the partnership establishes DeepScribe as the first company's first ambient AI solution partner, setting the stage to integrate DeepScribe's oncology-specific AI with Flatiron's proprietary platform, OncoEMR, which reaches 4200 providers in more than 800 community care sites in the United States.¹

"In recent feedback from oncologists, 91% called DeepScribe easy to use, with adoption rates over 80% within large oncology groups," Flatiron officials said in their statement.

"We are thrilled to partner with Flatiron and help them continue having a meaningful impact on cancer care," said Matthew Ko, DeepScribe CEO and cofounder. "We want to ensure that their clinicians can make the most of every encounter, with the information and time they need to truly connect with the patient. The seamless integration with OncoEMR helps make that happen."

DeepScribe provides clinical documentation for physicians and other medical providers; the "ambient AI" description refers to features that operate in the background, without requiring any proactive steps from the user to provide its solutions. DeepScribe transcribes medical visits in real time and adds key information, saving physicians time and allowing them to concentrate on patients. Of great importance, it integrates with electronic health records, which in the future could allow investigators to extract richer information from medical records for clinical trials and other studies.

According to the statement, DeepScribe's ambient AI is optimized for oncology "by understanding the workflow, terminology, and subtleties of

cancer care, automatically creating a structured clinical note." This includes extracting information from prior visits, gathering contextual information about the length between treatments from the current conversation, and including relevant International Classification of Diseases, 10th Revision diagnosis codes in the medical note.

"Technology—including AI tools—are transforming the point of care, improving outcomes for both patients and the clinicians who serve them," Nina Chavez, vice president of Strategic Partnerships and Alliances, Flatiron Health, said in the statement. "We're excited to bring DeepScribe's AI documentation tools to our network of providers, reducing the administrative burden on providers and enabling more meaningful time with patients."

Each AI-generated note automatically populates the patient chart within OncoEMR for clinician review and signoff, streamlining the workflow even further and giving clinicians more time in their day—and more time for care.

"Oncology care involves complex decision-making and information management," said Dean Dalili, MD, MHCM, DeepScribe chief medical officer. "Our teams have worked closely with oncologists for our AI to capture the nuances and details of a cancer care conversation. Oncologists tell us how well DeepScribe captures terminology, medication names, care plan details. We look forward to each Flatiron clinician benefitting—and in turn, each of their patients benefitting." ♦

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Banner Year for Bispecifics as Therapies Advance Into the Community Setting

RYAN FLINN

CONTINUED FROM COVER

“The democratization of bispecifics and cellular therapies is essential to allowing all these patients to access the most cutting-edge therapies,” Michael Byrne, DO, hematologist/oncologist at Tennessee Oncology, said during *Managed Care Case*, a podcast by *The American Journal of Managed Care*.⁴ “Those of us in community oncology are certainly capable of taking care of these patients either by ourselves or in partnership with a program or institution that can help navigate the early step-up doses with the goal of getting them back to their local clinics as quickly as possible for subsequent care.”

New Approvals

The year 2024 marked a notable expansion in this therapeutic class, with approvals of both new therapies and new indications for existing therapies (TABLE).⁵⁻⁹ These include: epcoritamab (Epkinly)⁵ for relapsed/refractory follicular lymphoma; tarlatamab (Imdelltra)⁶ for previously treated extensive-stage small cell lung cancer; zanidatamab (Ziihera)⁷ for previously treated unresectable or metastatic HER2-positive biliary tract cancer; zenocutuzumab (Bizengri)⁸ for previously treated non-small cell lung cancer and pancreatic adenocarcinoma with an *NRG1* gene fusion; and blinatumomab (Blinicyto)⁹ for consolidation in CD19-positive Philadelphia chromosome-negative acute lymphoblastic leukemia.

Real-world data presented at the 66th American Society of Hematology Annual Meeting and Exposition in December 2024 (ASH 2024) provided a first look at how quickly bispecific antibodies have been adopted in community oncology settings for multiple myeloma.² After the FDA's approval of teclistamab (Tecvayli) in late 2022, just 1 patient received this therapy compared with 148 on other treatments. Following the 2023 approvals of talquetamab (Talvey) and elranatamab (Elrexfio), usage grew to 45% of eligible patients, reaching 54% by mid-2024. Teclistamab dominated prescribing patterns in 91% of cases, with treatments distributed evenly across practices in the US.

Clinical and Development Updates

Several bispecific antibodies have reported clinical results and updates at recent medical meetings, business events, and industry conferences. Below is a snapshot of some of these developments.

BLINATUMOMAB. Results from a pivotal phase 3 trial (NCT03914625) presented at ASH 2024 and published in *The New England Journal of Medicine* showed that

adding blinatumomab to standard chemotherapy significantly improved outcomes, achieving a 3-year disease-free survival rate of 96% vs 88% with chemotherapy alone. Among Hispanic children, who historically face worse outcomes in leukemia care, blinatumomab extended disease-free survival by an additional 150 days.¹⁰

TECLISTAMAB AND TALQUETAMAB. At the 21st International Myeloma Society Annual Meeting (IMS 2024), investigator Yael Cohen, MD, head, Myeloma Unit, Tel Aviv Sourasky Medical Center, presented updated results from the phase 1b RedirecTT-1 study (NCT04586426).¹¹ The study evaluated a combination of teclistamab and talquetamab and reported an overall response rate of 80%, with 52% of patients achieving a complete response or better. The combination also demonstrated an 18-month progression-free survival rate of 70% and a duration of response rate of 86% at 18 months.

“Both of these agents are best-in-class bispecifics. They're performing very well from a competitive share standpoint,” Jennifer Taubert, executive vice president and worldwide chairman of innovative medicine at Johnson & Johnson, said during the company's earnings call on January 22.¹² “We've got them...being utilized in the academic setting, and we're working that out into more of the community setting, which will be important for their continued growth and uptake.”

EPCORITAMAB. Granted an accelerated approval in 2023 to treat relapsed/refractory diffuse large B-cell lymphoma (DLBCL), epcoritamab has demonstrated strong efficacy in previously untreated DLBCL. Data presented at ASH 2024 showed that combining epcoritamab with R-CHOP (rituximab, cyclophosphamide, doxorubicin hydrochloride, vincristine sulfate, prednisone) chemotherapy in untreated high-risk DLBCL achieved a 100% response rate and 87% complete response rate,¹³ with 83% of complete responders remaining in remission at 24 months. Data presented in May 2024 at the American Society of Clinical Oncology (ASCO) Annual Meeting showed that in previously untreated follicular lymphoma when combined with rituximab and lenalidomide, epcoritamab delivered a 95% response rate and 85% complete response rate.¹⁴

GLOFITAMAB. Marketed as Columvi, this bispecific antibody that targets CD20 on B cells and CD3 on T cells received accelerated approval¹⁵ in June 2023 for patients with DLBCL who had received 2 or more prior systemic therapies. Phase 3 trial results (NCT04408638)¹⁶ which were reported at the European Hematology Association Congress in June 2024, showed that combining glofitamab with

TABLE. FDA Approvals of New Bispecific Therapies, Indications in 2024⁵⁻⁹

Approved	Drug name	Manufacturer	Targets	Indication
May 16, 2024	Tarlatamab (Imdelltra)	Amgen	DLL3 and CD3	Previously treated extensive-stage small cell lung cancer ⁶
June 14, 2024	Blinatumomab (Blinicyto)	Amgen	CD19 and CD3	Consolidation in CD19-positive Philadelphia chromosome-negative acute lymphoblastic leukemia ⁹
June 26, 2024	Epcoritamab (Epkinly)	Genmab/AbbVie	CD20 and CD3	Relapsed/refractory follicular lymphoma ⁵
November 20, 2024	Zanidatamab (Ziihera)	Jazz Pharmaceuticals plc	Separate, overlapping domains of HER2	Previously treated unresectable or metastatic HER2-positive biliary tract cancer ⁷
December 4, 2024	Zenocutuzumab (Bizengri)	Merus N.V.	HER2 and HER3; inhibits <i>NRG1</i> binding	Previously treated non-small cell lung cancer and pancreatic adenocarcinoma with an <i>NRG1</i> gene fusion ⁸

Source: FDA

chemotherapy doubled survival for these patients at 26 months vs 13 months with standard therapy. The combination achieved higher complete response rates (59% vs 25%) and longer progression-free survival (14 vs 3.6 months). Additional studies in mantle cell lymphoma also showed strong responses. Notably, glofitamab is administered as a fixed-duration intravenous infusion over approximately 8.5 months, offering a time-limited treatment option.

IVONESCIMAB. This investigational bispecific antibody targeting PD-1 and VEGF is the first therapy to show a statistically significant improvement over pembrolizumab (Keytruda) in a head-to-head phase 3 HARMONI-2 trial¹⁷ called for PD-L1–positive non–small cell lung cancer. Beyond lung cancer, phase 2 data indicate promising efficacy in advanced triple-negative breast cancer, colorectal cancer, and head and neck squamous cell carcinoma, achieving response rates of up to 85% with a manageable safety profile.¹⁸

“Ivonescimab is effectively a unique mechanism of action from anything developed historically,” Maky Zanganeh, DDS, co-CEO and president of Summit Therapeutics, told attendees at the 43rd Annual J.P. Morgan Healthcare Conference on January 13. “Ivonescimab will continue to be rapidly tested, and its development advanced way beyond non–small cell lung cancer.”

Trispecific Antibodies

The next wave of therapies adds another element to create trispecific antibodies, which target 3 different antigens. Merck has made significant investments in this space by acquiring Harpoon Therapeutics in 2024 for \$680 million¹⁹ and gaining access to MK-6070, a trispecific T-cell engager targeting DLL3 in small cell lung cancer. The company also acquired Eyebio Limited,²⁰ securing Restoret, a trispecific for nononcology indications such as age-related macular degeneration and diabetic macular edema. The company is exploring combinations of trispecifics with other modalities, partnering with Daiichi Sankyo to add an antibody-drug conjugate in solid tumor trials.²¹

Johnson & Johnson is also experimenting with a trispecific combination targeting B-cell maturation antigen, GPRC5D, and CD3. Preclinical studies presented at ASH 2023 suggest that this approach could reduce antigen escape and improve immune-mediated tumor destruction.²² A presentation at IMS 2024 reviewed progress on this trispecific, known as JNJ-7965322, which essentially combines the targets of teclistamab and talquetamab but does so with much less toxicity.²³

A Robust Pipeline

The pipeline for these therapies continues to expand, with multiple drugs in late-stage development. A *Nature Reviews Drug Discovery* report²⁴ from March 2024 estimates more than 200 bispecifics were in clinical development at that time, with approximately half in phase 2 or 3 trials or already approved. These therapies target both hematologic malignancies and solid tumors, with T-cell engagers and immunomodulatory mechanisms dominating the field. Looking ahead, nearly 30 antibody-based therapies are under regulatory review globally, with 18 additional therapies expected to submit marketing applications by the end of 2025, including bispecific and trispecific treatments²⁵

“In the next few years, we’re likely to see [a] waterfall of new approvals, whether it be new drugs altogether, combination therapies, [or] therapies moving into earlier lines,” said Tyler Sandahl, PharmD, of Mayo Clinic, said during an interview with *Managed Care Cast*.⁴ “We just need to stay vigilant...and support our patients the best we can.”

Limitations

Although bispecific and trispecific antibodies offer new treatment options for patients, their clinical use is not without challenges. Unlike CAR T therapies, which are administered as a single infusion with potentially curative outcomes, bispecifics and trispecifics require frequent dosing—often weekly or biweekly infusions over an extended period. This ongoing treatment burden can be particularly taxing for patients who must regularly travel to infusion centers, especially those in rural or underserved areas.

Despite these differences, there are currently no consensus guidelines tailored specifically to bispecific antibodies, according to a 2024 report published in *Blood*.²⁶ Instead, management strategies are often adapted from protocols developed for CAR T therapies. The report recommended an approach that focused on proactive preparation, such as baseline testing and premedications, alongside patient and caregiver education to monitor for symptoms.

Practical Lessons for Clinicians

ASCO outlined some of the key steps clinicians need to be aware of when managing bispecific toxicities,²⁷ such as inpatient monitoring for teclistamab and talquetamab during dose escalation, unlike mosunetuzumab (Lunsumio), which can be administered in an outpatient setting. The article noted that collaborative care models, where community oncologists partner with academic centers for early treatment phases, can be critical for ensuring safety during higher-risk periods. Ensuring that clinicians and staff are up to date on the latest efficacy and safety data is also important, the article notes, as patients often rely on online resources (44%) and support groups (38%) for information about these therapies.

“By surmounting barriers to access and investing in the education of both providers and patients, the oncology community is paving the way for a future where advanced cancer treatments are accessible to all who need them, irrespective of their geographic or economic circumstances,” the ASCO article authors wrote. “The future of oncology care hinges not only on the development of novel therapies but also on the ability of our health care systems to adapt and provide these therapies to all patients in need.” ♦

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FROM OUR PARTNERS

As COA President, Patt Promotes Advocacy: “Each of Us Holds an Important Part of the Story”

MARY CAFFREY

CONTINUED FROM COVER

called the “middleman” in the US health care system. In an October 2023 appearance at a hearing of a House Energy and Commerce subcommittee, she was able to connect the dots between rising Medicare premiums and \$9 billion that had been repaid to hospitals due to a US Supreme Court ruling on the 340B program.³ In a separate visit, she offered powerful testimony about being told to wait, possibly up to 6 weeks, for a peer-to-peer consult regarding her 40-year-old patient with breast cancer, who was a candidate for an innovative treatment called monaCHER.⁴ Members of Congress were hearing directly from an oncologist how prior authorization can threaten a patient’s life.

“It’s incredibly frustrating for her—and for patients more broadly—because they feel like they don’t have any control over what’s going to happen, what their journey is going to look like,” Patt later told the American Medical Association.⁴

After years of advocacy, Patt becomes COA president just as bipartisan support is peaking for several of the most important items in the group’s legislative agenda. At the end of the last Congress, supporters of PBM reform succeeded in getting provisions into the original continuing resolution that was headed for then-President Joseph R. Biden’s desk, before then-President-elect Donald J. Trump called for a scaled-back resolution.⁵ Still, desire for PBM reform has not waned.⁶ Patt’s theme for the upcoming COA Conference, and for her tenure as COA president, “Empower and Advocate,” speaks to the need to maintain that momentum. Patt’s theme aligns with COA’s forthcoming release of the “Prescription for the American Health Care System,” which will detail its comprehensive policy agenda.

A board member for *Evidence-Based Oncology (EBO)*, she spoke with *EBO* in an extended interview about her plans as COA president as well as several key issues facing community oncology practices.

This interview has been lightly edited for clarity.

EBO: Can you discuss the theme, “Empower and Advocate”—the idea that empowering colleagues to advocate really extends to everyone?

PATT: I think COA does a great job of aggregating many different individuals [who] touch the community oncology ecosystem—doctors, nurses, administrators, pharmacists, advanced practice providers, patients, navigators—and so there’s an important role for everyone to be empowered and to advocate. We see a lot of challenges in public policy that pose a risk to community oncology. I think heightening awareness for various stakeholders is really important, as we each hold an important part of the story, sort of like puzzle pieces that you put together. Each of us holds an important part of the story about how to make a great community oncology practice. As an example, here in Texas, I serve as a vice president of Texas Oncology; frequently we have public policy meetings in our districts, and so either at a cancer center or at a local site, we will have a meal or a presentation with elected officials and have different people there—with patients, social workers, practice administrators and leaders, pharmacists, nurses, and doctors—and we each hold different pieces of how patients with cancer struggle in their communities, and what policy changes we could consider to try to make it better for patients.



PATT

Debra Patt, MD, PhD, MBA, FASCO, executive vice president, Texas Oncology; president, Community Oncology Alliance.

There are some obviously loud, resounding themes there that you've heard from COA before about things that can enhance community oncology. But it's really useful, actually, to hear everyone's perspective. As a doctor, I have one perspective about things such as prior authorization—the ability to give patients the first therapy that I want for them instead of fail-first step therapy limitations. [These] are great examples of things that I feel day to day. Or the issues of network inadequacy, as I try to call different primary care providers and beg for them to see my patients, because they're having a difficult time finding a primary care provider. Those are things [that I feel as the doctor], but there are different ways in which patients and patient advocates see the challenges in community cancer care; it may be in navigating their co-pay accumulator, it may be in getting their out-of-pocket costs reduced. It may be in managing the balance between their work and the therapy that they're getting. And again, social workers will look at things differently. Administrators will look at it differently. I think COA does a great job of aligning various stakeholders and educating them on how to advocate effectively and trying to bring us all together so that we all act as a team.

EBO: Let's discuss the policy agenda, because that's a big part of what COA hopes to advance this year. As we have this discussion (January 10, 2025), knowing how close advocates for PBM reform came in the last session, what do you look forward to this spring?

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PATT: I think that you are going to see a lot more advocacy and public policy from COA this year. It's always our strong suit, but you're going to see it even stronger and more coordinated as we think about our Prescription for the American Health Care System and engage with some new stakeholders, as the new administration comes into office and sets their priorities. I think what we've learned from the prior Trump administration is that there is an interest in managing “the middleman” or cutting out the middleman in care delivery. To me, that speaks to a prioritization on reining in pharmacy benefit managers—things that facilitate transparency and accountability, I think, make a big difference, and I suspect that will be a legislative priority this next year. I suspect that will be a priority for the administration in the next year.

In a similar vein, as you think about where you have costs in the health care ecosystem, the Trump administration previously did want to make changes in the 340B reimbursement. During the first Trump administration, there was a decrease in reimbursement to 340B programs. Now, that was not upheld at the Supreme Court level, but the Supreme Court's decision dictated that they required data to really think about reimbursement appropriately. We now have those data, so it would seem reasonable, for me, for the Trump administration to revisit the data and try to understand how that could influence 340B reimbursement, and particular action as it relates to child sites [off-site clinics not attached to the eligible hospital]. I believe 340B represented \$126 billion of drug purchasing last year,⁷ so it's a tremendous cost to the health care ecosystem.

Now, one thing about health care that I think is complicated is that you can't change everything perfectly so quickly. Because even if you think the reimbursement for 340B is inappropriate, it's hard to change everything all at once, because there are important parts of the ecosystem that have become dependent upon those finances. And so, I think it's going to take a really careful and thoughtful consideration about how to rein that [spending] in in a meaningful way, and how to create sustainable solutions.

Another area for all of medicine is in physician reimbursement. We've seen over the [past] 20 years a decrease of 28% in physician reimbursement,⁸ while there's been an increase in inflation and other things; it's created an issue of network inadequacy, where some doctors are not able [to accept patients] or some patients are not able to see doctors if they have Medicare as their primary payer. And we don't want that for American seniors. We want them to be able to access good primary care, good specialty care. There has to be a doc fix that's discussed early on in order to have a sustainable health care system.

EBO: You've also been very outspoken on the issue of prior authorization. We've seen a lot of activity on this issue in the United States; in the past few months, doctors have been going on social media and talking about experiences with their own patients with prior authorization. Has prior authorization reached a tipping point where something has to give?

PATT: Yes, I do think it has. Utilization management, or how insurance companies manage utilization, is important and complicated. But I do think that there are ebbs and flows to this, and it has definitely swayed so much that it is, right now, an inappropriate barrier and hurdle to patient care. So, we need the pendulum to swing in the other direction, because it's too prohibitive for patients to get the care that they need. This means that even though my reimbursement has declined, I have to employ people in my office just to manage the prior authorization. I have to write separate letters. Just last week, I was writing [a letter] for a pill for a patient with a high-risk breast cancer, and it's clearly FDA-approved; she clearly meets all of the inclusion criteria. This is on [National Comprehensive Cancer Network] guidelines. And I got pushback from the insurance and initial denial, and they need a letter of medical necessity. So, I wrote the letter of medical necessity, and my nurse spent several hours managing the appeal, and probably it will ultimately get approved. But the barrier of them doing an initial denial will cause some people to not get that therapy, and it's inappropriate for us to spend additional time and effort on doing that because that's time and effort that I'm not spending with other patients [who] need my service.

EBO: Let's talk about the Stark Law. I know COA has been working on this issue for a while—to advocate for oncology practices with pharmacies to be able to deliver prescriptions through the mail or give them to a caregiver who picks them up at the practice. There have been efforts at legislation.⁹ Since this problem arose due to an interpretation of the statute under the Biden CMS administrator, with the change of administration, is there a possibility of a regulatory fix?

PATT: You're talking about the fact that during the COVID[-19] pandemic, and even before that, we were all giving mail-order pills to patients. Frequently these are oral oncolytics; they represent about a third of the cancer therapies that we give today. And when patients could not come to the office and pick them up, we were able to send them by mail to patients, so they could take them to control their cancer. And that's really helpful. Again, I practice in the great state of Texas, and we see a lot of rural Texans in our cancer centers. For them to not have to come back to pick up a medication, it's really useful. And if they're at home, then they can't send someone else to do it, because after May of 2023, CMS put out an FAQ that said it's a Stark Law violation to send patients oral oncolytics in the mail to their home. And so, our ability to do that has gone away. We had a lot of success in passing legislation to address this in the last session. Rep Diana Harshbarger's [R, Tennessee] bill was passed in the [US] House [of Representatives] and then went over to the [US] Senate, and there was some discussion about including it in the continuing resolution. Ultimately, there just wasn't enough time to get it across the finish line. I think that there is bipartisan and bicameral support for the legislation, so I think it's going to need to be reintroduced. It's really important, particularly for rural Americans who require pills to treat their cancer.

EBO: In general, there seems to be a lot of interest in the concerns of rural medicine generally. And now we have a Senate finance chairman from Idaho [Sen Mike Crapo (R, Idaho)]. Are you optimistic that these concerns are going to receive a little more attention than they have in the past?

PATT: Yes, I am optimistic. Health care is complicated. I think that perspectives can be incredibly useful, especially for this issue.

I believe the secret sauce in medicine is the partnership between machine learning and AI, and the clinicians [who] deliver care and the staff that support practices, because I don't think any of them are going to act in a silo. It's always going to be a partnership. I think that AI will act as clinical decision support; that we'll be empowered to give patients better education. But there's a huge gap in educating the workforce in order to get us where we need to be.

EBO: I also want to ask you about a question about AI. You've spent most of your career working with technology in practice and now with AI in particular. Can you discuss the promise of AI in oncology but also the equity issues? How do we balance the potential while also ensuring that some practices are not left behind?

PATT: I'm so glad you asked. AI will touch every aspect of care delivery, from how we answer the phones, to how we communicate with patients, to how patients get screened, how their mammograms get read, how their colonoscopies get interpreted, how their pathology is read, how their diagnostic imaging is read, to the clinical decision support that manages the therapies that we prescribe, how each of our administrative partners work. So, I think it's going to be in every aspect, and I think that by and large, that will create efficiencies when we know how to use it. However, there are risks that need to be managed. Bias is one of them with the large language models; hallucinations is another, as is data fabrication. Those are some hazards and liabilities that need to be managed. But that said, error rates with large language models are incredibly low, and they continue to get better.

To err is human, and also to err is in machine learning. But it happens actually much less frequently in machine learning. I believe the secret sauce in medicine is the partnership between machine learning and AI, and the clinicians [who] deliver care and the staff that support practices, because I don't think any of them are going to act in a silo. It's always going to be a partnership. I think that AI will act as clinical decision support; that we'll be empowered to give patients better education. But there's a huge gap in educating the workforce in order to get us where we need to be.

So, I like to say that we have our North Star in sight, and we're sort of on a journey, but that journey will change as we go along that journey, and we need to do the important work of educating stakeholders on how to use these tools to make sure that they can improve community care as much as possible.

EBO: During the pandemic, we heard a lot about challenges with staffing in oncology, but we haven't heard as much recently, at least not reaching the level of press coverage. Where do things stand with staffing?

PATT: Staffing is a huge challenge. Nationally, [there are] nursing shortages. There are shortages in PET-Tech; there are shortages in radiation technologies. There are

a lot of shortages that we have that impact health care, and they are continuing to grow because of important issues such as the age distribution of the population and people needing additional services. So, supply is increasing and demand is decreasing. That's not a good setup. I think actually AI helps us here, not because it replaces the workforce—because I don't think that that's going to happen—but I think it can help our workforce act more efficiently.

I'll just give you an example. Today, when our triage nurses are managing patients who call in with symptoms, they're pulling up a symptom management pathway, and they're generating a note to the patient. They're generating a note to the chart. We're piloting a system right now that's AI-enabled that uses natural language processing to archive the note and then pulls up the pathway electronically and then prompts a note to the patient and a note to the chart. So how is that really different? It's clinical decision support that allows our nurses to act at the top of their license. And so, if our nurses are able to act at the top of their license, then they can spend more time being nurses, caring for patients, and not dictating the work that they're doing, which would be really helpful. I think we've seen the same thing in the Natural Language Processing ambient AI dictation system. So, in Texas Oncology, we've onboarded with DeepScribe; over the past year, most of our physicians [have been] using DeepScribe as an ambient AI language system [see related article, **SP106**]. I saw a patient this morning in clinic, and it was very complicated; her care is going to require lots of input from different doctors. Within 2 minutes of me leaving her room, her dictation was uploaded from the ambient AI listening server. I added a few pieces of information and sent it off immediately to my referring providers, whose help I will need with her care. So, that really has been able to help a lot.

If we can make people's jobs easier, we do a better job at managing the staffing shortages that we have, and we do a better job at managing burnout. I've called it to my partners, affectionately, the "Home for Dinner" campaign that I want to start using these digital tools so we can get home to our families for dinner. But whatever it is you want to get home to, if it's not your family for dinner, if it's to an exercise class, or to something else enriching that you do, we all require work-life balance, and I think AI gives us great promise of the ability to help us.

EBO: That connects to the issues of burnout and staffing and all the other things that we're hearing about. If you can connect it to those things, I would imagine that helps with getting doctors' buy-in for the technology.

PATT: You know we are going to have to teach a few old dogs new tricks. And that's a process. I think it's a process that's going to require a lot of education and knowledge. I think I have some friends across the country [who] are trying to help with this issue of heightening awareness of AI systems, to try to help oncology navigate this space better, and I think that's really important work. ♦

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