TRANSLATING HEMATOLOGIC ONCOLOGY DISCOVERIES INTO PRACTICE

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PHYSICIAN'S WEEKLY

TURNING MEDICAL MISINFORMATION INTO MEANINGFUL PATIENT CONVERSATION

Alex McDonald, MD, explains how physicians can navigate polarized health conversations by replacing sound bites with nuance, curiosity, and trust—turning disagreement into connection with practical strategies that strengthen patient relationships and improve outcomes.

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Immunotherapy Transformed Oncology, But Infrastructure and Funding Barriers Still Limit Who Benefits

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Building the Plane As We're Flying It: Sequencing Immune Therapies in Multiple Myeloma

Rahul Banerjee, MD

The treatment landscape for relapsed or refractory multiple myeloma (RRMM) has changed considerably in recent years. Two published phase 3 trials, CARTITUDE-4 and MajesTEC-3, have both demonstrated improved progression-free survival, improved patient quality of life, and improved overall survival (OS) with chimeric antigen receptor T-cell (CAR-T) therapies and bispecific antibody (bsAb)–based combinations versus standard options. We spent years as a field saying that OS was no longer a realistic goal in multiple myeloma (MM), given the rapid advancement of therapies at subsequent relapse. As it turns out, though, CAR-T therapy and bsAb-based combinations targeting B-cell maturation antigen (BCMA) work so extraordinarily well that they can, in fact, move the needle on OS when positioned early enough.

The question is thus no longer whether to use CAR T cells or bsAbs, but rather when to use them—and which one to choose first. Once the combination of teclistamab and daratumumab (tec-dara) from MajesTEC-3 is approved in the United States, these questions will get messy quite quickly. By the book, the International Myeloma Working Group (IMWG) guidelines recommend the prioritization of CAR-T therapy over bsAb therapy for patients who are clinical candidates for both. This message still resonates with me and with many of my patients: CAR-T therapy involves a one-time infusion followed by observation, with one-third of CAR-T therapy recipients in the CARTITUDE-1 trial still living well at the 5-year mark with zero myeloma treatments. If a cure for myeloma exists, CAR-T therapy is the surest ticket there with the information and treatments we currently have available.

But there are important caveats to this. First, there is no head-to-head trial of BCMA-targeted CAR-T therapy versus BCMA-targeted bsAb therapy. Even if such a phase 3 trial could be funded, the details would be quite challenging. All phase 3 CAR-T therapy trials to date have used the control arm as the basis for pre-infusion bridging in the CAR-T arm, so would you use a BCMA-targeted bsAb for bridging in the BCMA CAR-T arm? (Doing so runs the risk of dramatically inferior outcomes.) Or would you use a non-BCMA bsAb such as talquetamab as bridging in the BCMA CAR-T arm? This strategy works well, but how would you isolate the effect of the bsAb bridging versus the CAR-T therapy itself to see whether it was superior?

Then, much more importantly, there are huge disparities in access to CAR-T therapy—both across the United States and across the globe. For my patients in Alaska and Montana (where no CAR-T therapy centers exist), what decision would they make if tec-dara were approved and available at a center near them? The aforementioned calculus, with CAR-T therapy being a one-time infusion versus indefinite bsAb-based therapy, still applies, but the daunting logistics of being asked to uproot one's life to move to a big city for several months can be formidable. I had the privilege of giving an MM-focused talk in Istanbul, Turkey, earlier this year, and I learned that there is one BCMA-targeted bsAb therapy but zero BCMA-targeted CAR-T therapies available across the entire country, which includes more than 80 million people. I can wax poetically all I want about CAR-T versus bsAb therapy in terms of comparative clinical efficacy, but this distinction will not be relevant for many segments of the world that have access to only one of the two (if any at all).

Returning to the lack of randomized data to compare CAR-T therapy versus bsAb therapy in MM, another challenge is that neither the CARTITUDE-4 nor the MajesTEC-3 trial truly represents the modern US patient with MM. For example, only a quarter of CARTITUDE-4 patients and 5% of MajesTEC-3 patients had previously received daratumumab, a drug that I have been giving to 100% of my patients with

newly diagnosed MM for almost 5 years. Even if the perfect randomized trial between the two modalities can be run, there would be nuances in real life that a trial could never predict. For example, the hypothetical patient who starts treatment with tec-dara with their primary oncologist but then has second thoughts and decides to see me to discuss BCMA CAR-T therapy after being BCMA exposed. And of course, trials of time-limited bsAb therapy are ongoing. Our IMWG sequencing guidelines favoring CAR-T therapy over bsAb therapy in the general sense are based on data from indefinite bsAb therapy in heavily pretreated patients. As better time-limited bsAb-based combination regimens emerge, how will this calculus change? To be honest, I have no idea.

Once tec-dara is approved in the US, our decision-making paradigm around T-cell therapies will feel like building a plane as we're flying it. Even as I wrap my head around CARTITUDE-4 versus MajesTEC-3, along will come MajesTEC-9 (which reportedly has already shown an OS benefit in daratumumab-exposed RRMM versus standard treatments) and then studies of frontline CAR-T therapy (eg, CARTITUDE-6) to disrupt whatever framework I have built. We will thus continue to make educated guesses based on the data we have available, coupled with our experiences. Ultimately, when the question of "Is CAR-T or bsAb therapy the best choice for me?" arises, the short answer will be "Yes." The longer answer will need to take the patient's values and logistical circumstances into account, but both choices will ultimately be right.

"The question is thus no longer whether to use CAR T cells or [bispecific antibodies], but rather when to use them—and which one to choose first."

—Rahul Banerjee, MD, Assistant Professor, Fred Hutch Cancer Center

The Art and Science of Community Hematology Practice in 2026

Lessons of Coordinated Care From the Emerging Understanding of Clonal Hematopoiesis

*By **Kimberly Ku, MD***

The American Society of Hematology (ASH) educational publications emphasize that clonal hematopoiesis of indeterminate potential (CHIP) serves as a systemic biomarker, contributing not only to hematopoietic aberrations, but also to cardiovascular disease and solid tumor outcomes.[1] The cause of death for most patients is not myeloid transformation, but rather cardiovascular disease, primary malignancies, and comorbidities.[1] CHIP carries an annual rate of progression to myeloid neoplasms of only 0.5% to 1.0% and therefore is not an immediate cancer diagnosis.[2,3]

Although ASH guidelines provide frameworks for diagnosis and monitoring, no evidence-based consensus criteria exist for therapeutic intervention. Multiple clinical trials are underway to evaluate interventions targeting underlying inflammation and clonal dynamics, to name a few: IDH1/2 inhibitor studies for clonal cytopenia of undetermined significance (CCUS) in North America,[4] anti-inflammatory approaches including the TECTONIC trial (NCT06691217) testing IL-1β inhibition on vascular inflammation and clonal dynamics in *TET2* clonal hematopoiesis (CH) and the ZEUS trial (NCT05021835) evaluating IL-6 inhibition with ziltivekimab, and the LoDoCo2 substudy demonstrating that low-dose colchicine modestly reduced *TET2* variant allele frequency over time.[5] However, no current published studies are available to demonstrate that identifying CH through expert review and implementing cardiovascular risk reduction strategies improve cardiovascular outcomes compared with standard risk factor management.

American Society of Hematology educational materials emphasize that establishing standardized diagnostic criteria, harmonizing trial frameworks, and formally incorporating CHIP into hematology, cardiology, and survivorship paradigms will be essential to reducing long-term morbidity.[1]

The National Comprehensive Cancer Network (NCCN) provides the most comprehensive US-based guidance on CH and precursor conditions,[2] with additional insights from ASH educational publications,[1] although formal consensus statements from major societies remain limited.

The NCCN Myelodysplastic Syndromes (MDS) Guidelines provide a structured framework distinguishing CHIP, idiopathic cytopenia of undetermined significance (ICUS), and CCUS based on the presence of cytopenias, clonality, and transformation risk:

- **CHIP:** CH without cytopenias; observation with monitoring based on clinical change
- **ICUS:** Cytopenias without clonality; observation with yearly monitoring
- **Lower-risk CCUS:** Cytopenias with clonality but lower transformation risk; observation with yearly monitoring
- **High-risk CCUS:** Cytopenias with clonality and higher transformation risk; observation with monitoring two to four times yearly for CBC; clinical trial consideration

The NCCN endorses the Clonal Hematopoiesis Risk Score (CHRS), which stratifies patients into low (CHRS ≤9.5), intermediate (CHRS 10-12), and high (CHRS ≥12.5) risk categories with myeloid neoplasm risk increased 3-, 37-, and 348-fold, respectively, compared with patients without mutations. High-risk CH confers mortality risk similar in magnitude to that of heart failure, with nearly 60% of the high-risk group dying during follow-up compared with a mortality rate of approximately 20% among low-risk individuals.[2] High-risk features include variant allele frequency of more than 10%, two or more somatic mutations, spliceosome gene mutations (eg, *SF3B1, SRSF2, U2AF1,* and *ZRSR2*), or mutations in *RUNX1* or *JAK2,* which have positive predictive value for myeloid neoplasms. Hence, accurate risk stratification requires specialized molecular testing as a part of expert hematopathology review.

Distinguishing CH from early MDS represents a significant challenge because these conditions share an overlapping mutational landscape. The presence of MDS-associated gene mutations does not establish a diagnosis of MDS in the absence of clinical diagnostic criteria, yet establishing a diagnosis of MDS is often challenging in the absence of clear morphologic dysplastic changes or MDS-specific cytogenetic abnormalities.

Expert hematopathology review leads to diagnostic reclassification in approximately 9% to 40% of cases, with

major diagnostic changes occurring in 5.9% to 24.3% of cases. These relatively large ranges reflect how precise data on CH reclassification rates remain limited.[6]

The available evidence suggests that while expert hematopathology review frequently leads to diagnostic refinement in hematologic disorders, the specific impact on CH diagnosis and management warrants dedicated study. Published outcomes data specifically quantifying the impact of diagnostic reclassification or management changes after expert review in cases of CH remain extremely limited because most available evidence focuses on natural history and risk stratification rather than the clinical benefit of expert-driven interventions.

In a tertiary cancer center study of 78 patients with CH, researchers found that most deaths were related to primary malignancies (35%), comorbidities (20%), or myeloid neoplasms (20%), with a median overall survival of not reached and a 2-year survival rate of 79%.[7] Transformation to myeloid neoplasms occurred in 15% of cases, with the 3-year cumulative incidence higher in CCUS (21%-24%) than CHIP (6%). This study highlights that patients die more frequently from their primary malignancy or comorbidities than from myeloid neoplasms, suggesting that accurate diagnosis and risk stratification may prevent overfocus or treatment from the hematologic perspective of myeloid neoplasms.

"Distinguishing CH from early MDS represents a significant challenge because these conditions share an overlapping mutational landscape."

At Mayo Clinic's clonal hematopoiesis clinic, patients at low risk often have care de-escalated after expert review, suggesting that initial referrals may include "overcalls" or diagnostic uncertainty.[8] While this finding implies potential reduction in unnecessary interventions, anxiety, and healthcare costs, no published data quantify these benefits in terms of quality-adjusted life years, healthcare utilization, or patient-reported outcomes.

A study examining 36 patients with known antecedent CH that transformed to myeloid neoplasms found that the median time to transformation was 15 to 26 months, with a median overall survival from the time of myeloid neoplasm diagnosis of 54 months for MDS, not reached for chronic myelomonocytic leukemia, and only 2 months for acute myeloid leukemia.[8] Most patients had expansion of their CH-mutated clone at transformation, and some acquired new driver mutations. This suggests that close monitoring may enable earlier detection of transformation, although whether earlier detection translates to improved survival, patient-reported outcomes, or healthcare utilization requires further evidence.

A hub-and-spoke model may help improve our study of CH by centralizing complex research/therapies at a "hub" (major center) and extending access/data collection via "spokes" (community clinics/hospitals) for broader patient recruitment, standardized care, and real-world evidence. This may enable efficient and more aligned management of CH-linked risks such as cardiovascular disease or cancer and improve access to specialized diagnostics and treatments through clinical trials for diverse populations.[9]

Integrating a collaborative model, as described previously, may help employ randomized or other experimental designs comparing outcomes between patients receiving expert hematopathology review and those receiving standard community care, measuring not only hematologic progression but also healthcare utilization, patient-reported outcomes, cardiovascular events, quality-adjusted life years, and cost-effectiveness.

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Blood Cancers Today spotlights the latest research from medical residents and fellows in the field of hematologic malignancies.

After Transplant: A Fellow's Role in Uncovering Gaps in Survivor Care

*By **Nichole Tucker***

Completing both residency and fellowship at Duke University School of Medicine was the springboard that propelled **Allison Taylor, MD,** into a focus on myeloid malignancies and deepened her understanding of healthcare disparities, from the system level down to the patient. Driven by a curiosity to uncover inequities, she contributed to research examining how social determinants influence outcomes and shape clinical adherence to late-effect screening in survivors of allogeneic hematopoietic cell transplantation (allo-HCT) across the US.

Allison Taylor, MD

"There's very minimal insight into how social drivers of health affect survivorship screening, even though we know they impact access to transplant and posttransplant outcomes, Dr. Taylor told *Blood Cancers Today* in an interview. "It's unclear which aspects of posttransplant outcomes are most influenced—especially when it comes to something as critical as survivorship screening."

The research began with taking a retrospective look at patient records from 22 centers in the US. The patients included in the cohort had been disease free for 3 or more years. Extracting key information from the electronic medical records, Dr. Taylor and colleagues defined clinical adherence to late-effects screening as order or test completion within 11 months to 2 years after allo-HCT. The investigators determined that optimizing long-term care for allo-HCT survivors required tailored interventions.

Among the 500 patients analyzed, social determinants of health (SDOH) variables were available for 374 individuals. The median age at the time of HCT was 47 years (interquartile range, 21-60); 58% were male, 83% were White, and 12% were Hispanic. The analysis revealed that socioeconomic and structural factors were associated with differential adherence to posttransplant screenings. Dr. Taylor said, "Our research showed that patients living in areas with lower education levels and higher poverty were less likely to receive both invasive and noninvasive screening."

Decreased cancer screening was observed among individuals with less than a high school education. Dual-energy x-ray absorptiometry testing was inversely associated with increased internet access but positively associated with renting a home. Vitamin D screening increased among patients receiving supplemental security income and those without personal vehicles.

Fasting glucose screening was associated with direct purchase insurance (DPI) and renting a home, whereas greater internet access corresponded to decreased screening. Lipid screening was more frequent among patients with DPI but decreased among individuals with income below the poverty line and those with less than a high school education. Renal function screening correlated positively with supplemental security income, Medicaid enrollment, and lack of personal vehicles.

"Gaps in screening depend on the individual," Dr. Taylor said. "Factors like insurance, transportation, and the ability to take time off work all play a role." She noted some unexpected patterns: "Some of our findings were surprising—like increased screening in areas with more renting or less car ownership—which raises questions about how we define socioeconomic disadvantage." Collectively, these findings highlight how structural and socioeconomic factors influence adherence to recommended post-HCT screenings.

However, these results do not capture the full complexity of clinician-patient interactions or the conversations that help determine whether screenings are ordered and completed. Although SDOH clearly influence adherence for certain tests, the study could not explain why some survivors received care while others did not. These gaps highlight the need for strategies adapted to local contexts that address both patient-level barriers and system-level challenges, as well as further research to understand unexpected patterns related to internet access, housing, and transportation.

"To design meaningful interventions, we need to go back to the community and actually talk to survivors about the challenges they face," Dr. Taylor said, highlighting the next step in translating these findings into actionable improvements in survivorship care.

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Get to Know

Learn more about the leaders, innovators, and educators in hematologic oncology.

Mansi Shah, MD

Dr. Shah discusses her love for travel, the importance of time-limited therapies in myeloma, and how she expands access to patient care through community partnerships at Rutgers Cancer Institute.

*By **Melissa Badamo***

As the clinical director of multiple myeloma at Rutgers Cancer Institute and an assistant professor of Medicine at Rutgers Robert Wood Johnson Medical School in New Jersey, **Mansi Shah, MD,** is driven by delivering cutting-edge therapies to patients with multiple myeloma in the Garden State.

Originally planning to focus on leukemia, Dr. Shah recalls her first experience learning about cancer when her friend was diagnosed with leukemia at the age of 6.

"That sparked my interest in blood cancers," she reflected. "I wanted to find out the science behind it and how you fix it."

Now, as a myeloma specialist, her clinical research focuses on improving treatment through cellular therapies such as chimeric antigen receptor (CAR) T-cell therapy and bispecific antibodies.

"Myeloma is at the forefront of immunotherapy," she said. "Transplants were used in myeloma from the get-go, and there's a lot of immunology and science behind it. People are living longer. Myeloma has become a chronic disease. There are so many new drugs in the pipeline, and I wanted to be a part of that group that's using those new drugs and forwarding the research."

Dr. Shah describes treating myeloma as a whole-person approach. "These patients stay with you for a long time," she said. "I essentially become a second primary care doctor for these patients."

A New Wave of Immunotherapy

During medical school at Robert Wood Johnson, Dr. Shah was heavily inspired by **Roger Strair, MD,** the chief of blood disorders at Rutgers Cancer Institute, who expressed an unwavering passion for research and translational science. After relocating to Philadelphia for her residency at Jefferson Health, Dr. Shah moved back to Rutgers, where she is currently studying the bispecific B-cell maturation antigen (BCMA)–directed CD3 T-cell engager linvoseltamab as treatment for patients with newly diagnosed multiple myeloma. The single agent produced "excellent response rates" of 85% to 86%, according to Dr. Shah.

"It's another data point that's changing the paradigm for the treatment of newly diagnosed multiple myeloma," she said. "Instead of adding more agents, maybe if we use selected agents or immunotherapy, we might get the same results or better."

Dr. Shah is also participating in a clinical trial of arlocabtagene autoleucel, a GPRC5D-trageting CAR T-cell therapy, for patients with myeloma. Moving forward, she hopes to see more time-limited therapy emerge within the next 5 to 10 years, potentially leading to longer periods of remission.

"I hope to see patients getting some amount of definite treatment and then be able to participate in their life the way they would like to," she said. "I also hope to see increased uptake in not just larger academic centers, but also across the board, because getting care closer to home is very important."

Expanding Cancer Care Through Community Partnerships

At Rutgers, Dr. Shah is working with community partner sites to reduce travel for patients, streamline operations, and standardize how care is administered.

"Part of what I'm doing here at Rutgers is trying to get newer therapies and allowing them to be used across our

health system so patients don't have to travel several hours to a main academic site," she explained. "Instead of a hub-and-spoke approach, we do a spoke-and-spoke approach where there is local expertise. If we can provide the same care at our main site as well as a local site—whether it's a clinical trial or standard-of-care therapy—that's the ultimate goal."

"If we can provide the same care at our main site as well as a local site—whether it's a clinical trial or standard-of care-therapy—that's the ultimate goal." *—Mansi Shah, MD*

To expand access to care, Rutgers Cancer Institute opened The Jack & Sheryl Morris Cancer Center in partnership with RWJBarnabas Health in mid-2025. The Vogel Medical Campus is slated to open in 2027 at Fort Monmouth in Tinton Falls, New Jersey.

"The goal is to have care and clinical trials closer to home, because I don't want people to have to cross the river into New York City to get the care that they need," she said.

The proudest moment of Dr. Shah's career is creating a care network at Rutgers by cultivating relationships with pharmaceutical companies and other partner sites across New Jersey.

"I'm driven by getting new therapies to patients wherever they are," Dr. Shah said. These new therapies include teclistamab, another BCMA-directed CD3 T-cell engager, which was approved by the FDA in late October 2022.

"We were able to use it commercially the first week of November for a patient who really needed it," she recalled. "This was a big effort on everyone's part to get everything operationalized. Sometimes, it takes months to get a new drug on the market into practice. We did it within a couple of weeks, and I'm very proud of that."

Reflecting on her accomplishments, Dr. Shah also offered advice for younger physicians or trainees who share the same passion for delivering cutting-edge therapies to patients.

"You have to find your anchor, because this is a very tough field emotionally and psychosocially," she advised. "You have to find something that continues to drive you. The ups and downs of a patient's journey may deter you, but if you find that anchor or passion to get new drugs to patients, focus on that."

A Passion for Travel, Food, and Culture

Dr. Shah moved from continent to continent growing up, partly due to her father's occupation as a general practitioner. As a result, travel was ingrained in her at an early age, a passion that remains a significant part of her life today.

"I've grown up traveling and learning about new cultures," she reflected. "I'm a vegetarian, so my goal when traveling is to find good vegetarian food. I also really enjoy cooking. I can't say I'm a top chef, but I pretend that I'm on *Chopped*!"

Dr. Shah's ever-growing travel bucket list includes Uzbekistan, Tajikistan, New Zealand, and the Great Migration in Africa.

"I enjoy traveling to different countries in Asia because of the food, the spices, and the different textures and tastes," she shared. "There's also a sense of friendliness in Asia. It's a community-based culture, and that's also at the core of who I am."

PHOTO CREDIT: istock.com/KOJ.art

AML World Awareness Day

The acute myeloid leukemia (AML) field has witnessed a surge of novel treatment options, with venetoclax-based strategies taking the forefront of novel combinations. For example, the RELAX trial showed that venetoclax added to high-dose cytarabine and mitoxantrone can reach a composite complete remission rate of 75%, compared with 50% for cytarabine-based salvage alone, without additional toxicity.[1]

In the phase 2 Paradigm trial, azacitidine added to venetoclax showed superiority compared with chemotherapy in terms of quality of life, symptom burden, and depression symptom scores, with an overall response rate of 88% versus 62% and a composite remission rate of 81% versus 55%.[2] Meanwhile, early phase 1 results report a robust safety profile when venetoclax is added to ruxolitinib, with plans to add a hypomethylating agent in future studies.[3]

Despite these advancements, there are still many remaining unmet needs for this fast-growing disease, as the success observed with venetoclax-based combinations may not reach patients with ***TP53*** mutations. In honor of AML World Awareness Day on April 21, AML experts described the meaning of this day and outlined remaining unmet needs in AML.

Mikkael Sekeres, MD
Chief of the Division of Hematology
Sylvester Comprehensive Cancer Center

What does AML World Awareness Day mean to you?
To me, AML World Awareness Day symbolizes the incredible strides we have made in the treatment of AML, the transformation of this once intractable disease to one that is often curable, and the opportunities we have to make the lives of our patients even better.

What are the remaining unmet needs in AML?
Until we have cured 100% of people diagnosed with AML, the unmet needs are to cure those whose disease persists and to uncover the biology of this disease to make that goal achievable.

Maximilian Stahl, MD
Director of the Leukemia and Myeloid Malignancy Program
Yale Cancer Center

What does AML World Awareness Day mean to you?
To me, AML World Awareness Day is a day of visibility. In my clinic, I see the immense courage of patients facing a diagnosis that is often sudden and life-altering. In my research, I see the complexity of the disease we are fighting to understand. This day means we are making the invisible visible—reminding our patients that they are not alone in this fight and reminding the world that while AML is aggressive, our collective resolve to overcome it is even stronger. It is a day to celebrate the survivors, honor those we have lost, and reaffirm our promise to never stop searching for better answers.

What are the remaining unmet needs in AML?

Overcoming Resistance and Relapse
The "Whack-a-Mole" nature of AML—where one clone is suppressed only for another to emerge—remains our greatest scientific hurdle. We need to better understand the leukemic stem cell and develop "triplet" therapies or sequential treatments that prevent the disease from evolving around our current targeted inhibitors (like FLT3 or IDH1/2).

The "Ultra-High-Risk" Challenge: TP53 *Mutations*
Perhaps the most sobering unmet need is the management of *TP53*-mutated AML. While we have made strides in other genetic subsets, *TP53* remains our most formidable adversary. Traditional "7+3" chemotherapy and even newer venetoclax-based combinations often fall short here because *TP53* is the "guardian of the genome"—when it is broken, the cell simply refuses to undergo programmed death.

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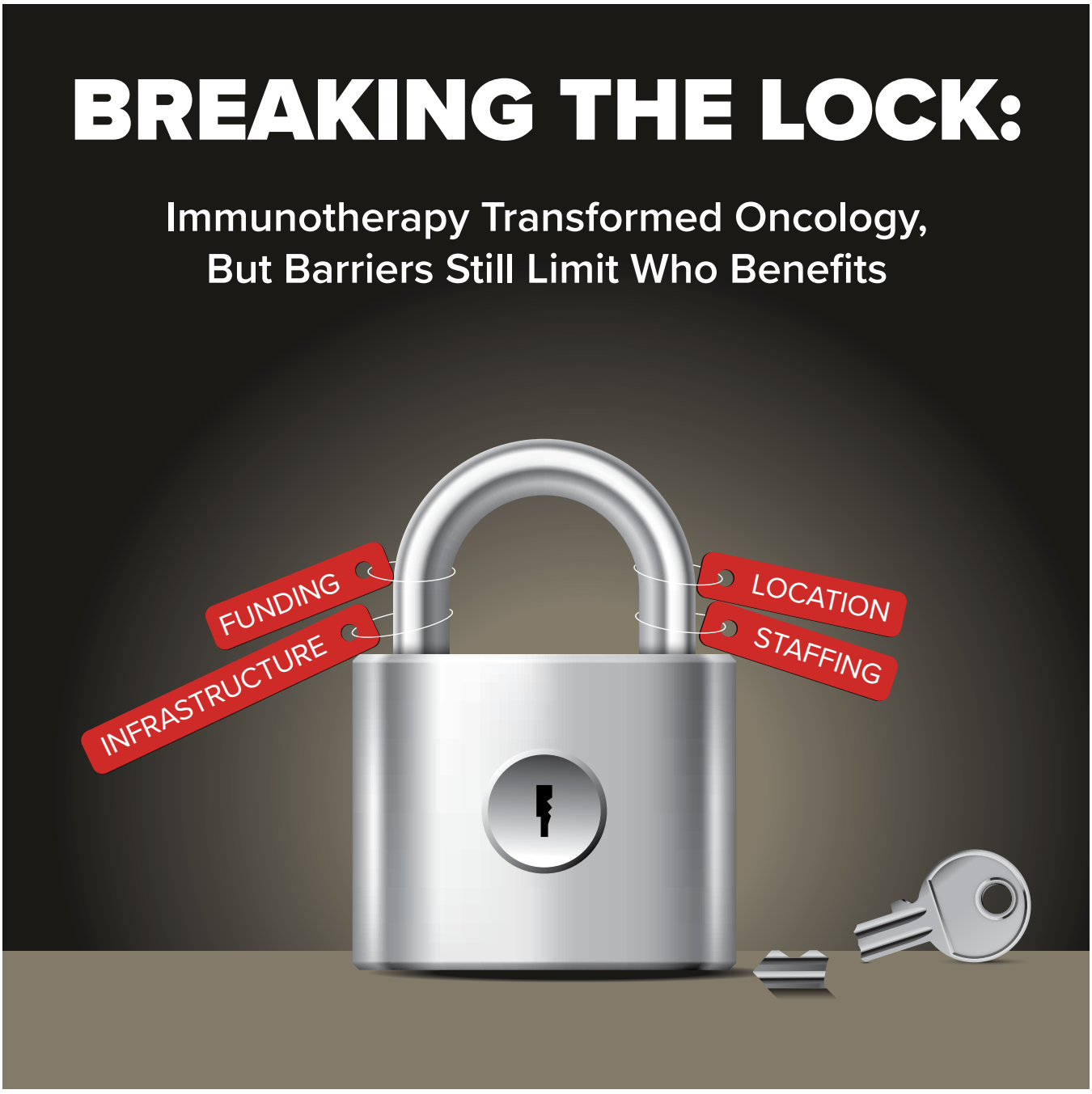
In Focus

Blood Cancers Today *takes an in-depth look at hot topics in hematologic oncology.*

BREAKING THE LOCK:

Immunotherapy Transformed Oncology, But Barriers Still Limit Who Benefits



By ***Sara Karlovitch***

Recent progress in blood cancer treatment has been largely powered by advances in immunotherapy trials. Apart from the introduction of rituximab in 1997 for the treatment of non-Hodgkin's lymphoma, the major immunotherapy advances driving modern cancer treatment, such as the introduction of tisagenlecleucel and nivolumab in 2016 and 2017, respectively, have only been around for approximately a decade.[1]

However, access to lifesaving clinical trials is not universal, and not every patient can obtain cutting-edge treatments. Even if they can access advanced cancer therapies, the outcomes can vary widely based on location. A center in an urban area may have better results across the board than a center in a rural location.

Location is just one factor when it comes to successful implementation of complex therapies. Funding, staffing,

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and infrastructure considerations all play into the success of executing the results of clinical trials in community oncology centers. These barriers to access are reflective of the hurdles around clinical trial enrollments, which made immunotherapy possible in the first place.

"While community oncology practices deliver cancer care to 85% of Americans with cancer, they face systematic barriers that prevent them from offering clinical trials to their patients," said **Kashyap Patel, MD,** a former Community Oncology Alliance president and the CEO of Carolina Blood and Cancer Care Associates. "This creates a two-tiered system where access to experimental therapies depends on geography and socioeconomic status rather than clinical need."

The outcomes created by these barriers can be significant, including widening racial disparities in health, worse patient outcomes overall, and reduced validity of the study overall. However, steps can be taken to close gaps and improve results.

The Implementation Barrier: Location

Location remains a major barrier to both clinical trial access and the availability of advanced cancer therapies. Clinical trials and cutting-edge immunotherapy tend to be concentrated in urban settings with large academic centers, largely neglecting rural and suburban centers. This leads to lower enrollment in clinical trials by rural populations, leading to trial underrepresentation and potentially widening health disparities between rural and urban populations.[2]

"Rural Americans living hours from academic centers face prohibitive travel burdens for trial participation. Each trial visit may require hundreds of miles of travel, overnight accommodations, and time away from work—particularly challenging during active cancer treatment," said Dr. Patel.

Beyond clinical trials, rural patients tend to have less access to life-saving cancer treatments compared with their urban counterparts. A 2023 study published in *JAMA Oncology,* "Adoption of Innovative Therapies Across Oncology Practices—Evidence From Immunotherapy," found that adoption of immunotherapy within 2 years of FDA approval was 11 percentage points lower at rural practices compared with urban practices. This is despite the fact that barriers to administering immunotherapy are quite low, as the treatment doesn't require the same level of specialized training and equipment as other complex and cutting-edge therapies.[3]

Overcoming the location barrier is tricky. For many, frequent visits to an urban academic center for treatment are just not feasible, given the time and money needed to do so. This leads to low recruitment, a major cause of early-trial termination.[4]

One solution to closing the gap in the delivery of advanced therapy may be limiting the number of visits the patient needs to make to a large center. This would require teamwork between the patient's team and the large center, along with virtual monitoring.

"I need to see the patient initially, because then we develop a relationship. And then what happens is that we can do the high-end therapy at a close major center, which is sometimes once every month or every several weeks," said **Michael K. Wong, MD, PhD,** physician-in-chief at Roswell Park Comprehensive Cancer Center. "And then you follow them out in the community, and working in close collaboration with that patient's medical caregiver … is very, very important. And virtual visits help."

Communication between larger academic centers and community centers is crucial for the successful adoption of new therapies. Oncologists should be in frequent touch with clinical experts, even for drugs that seem straightforward, to prevent adverse effects.

"When using new therapies for the first time, it is imperative to discuss these patients with clinical experts," said **Nicholas Short, MD,** an associate professor of leukemia at The University of Texas MD Anderson Cancer Center. "There are nuances to using many of these drugs even when they seem 'simple,' such as a new oral therapy. However, there may be monitoring requirements that physicians should be aware of, challenges with toxicity management, etcetera."

"Every approved therapy should be tested in populations representing its intended use. Every community practice with clinical expertise should have the opportunity to participate in advancing cancer research."

—Kashyap Patel, MD, CEO of Carolina Blood and Cancer Care Associates

The Implementation Barrier: Finances

Location barriers and financial barriers tend to go hand in hand for both patients and oncologists. Rural community oncology centers tend to not have the same funding levels as larger, urban, academic centers. In addition, many patients in rural communities lack the funding to travel to urban centers.

Clinical trial funding largely comes from the National Institutes of Health and the National Cancer Institute. However, this funding is largely concentrated at academic institutions. Also, funding from these sources usually only covers some of the associated costs. Large organizations are in a better place to cover those costs compared with community centers.[5]

"Community practices receive only 20% to 25% of the per-patient funding that academic medical centers receive for identical trial deliverables," said Dr. Patel. "This financial inequity, combined with limited network access and insufficient infrastructure support, makes trial participation financially

unsustainable for most community practices. The result is concentration of clinical trials in urban academic centers, effectively excluding rural and underserved populations from participating in cutting-edge cancer research."

The finances of oncology centers is just one part of the equation. Patient income is a major factor to clinical trial access, immunotherapy use, and overall outcomes. A Research Letter published in *JAMA Oncology* noted that patients with a household income below $50,000 were 27% less likely to participate in clinical trials.[6]

A patient's income can also affect their immunotherapy use. A 2023 analysis published in *Scientific Reports* showed that patients with advanced-stage non–small cell lung cancer and lower socioeconomic status were less likely to receive the treatment in the years immediately after approval. Beyond immunotherapy, lower-income patients were 17% less likely to receive precision therapy overall.[7]

The Implementation Barrier: Infrastructure

Infrastructure barriers are closely entwined with financial and location barriers. Staffing, availability of necessary equipment, and other challenges remain significant hurdles for oncologists looking to offer advanced and cutting-edge trials and therapies to their patients.

The same 2023 article published in *JAMA Oncology,* which revealed that rural patients were 11 percentage points less likely to receive immunotherapy compared with those living in urban areas, also found that that the number of physicians at a practice has an even greater impact on immunotherapy uptake. Patients who attended a practice with one to five physicians were 27 percentage points less likely to receive immunotherapy than those who went to a clinic with six or more physicians.[3]

One way of combating this disparity is through a robust dialogue between smaller community centers and larger academic ones. This could help to mitigate some of the risks associated with implementing advanced therapies. Because clinical trial populations tend to be narrower than the overall population, it can be difficult to apply certain results to a more general patient population.

"Proper patient selection is important, and it can be challenging to extrapolate clinical trial findings to other populations," said Dr. Short. "Ideally, these patients are treated at high-volume centers. When not feasible, we recommend close partnership with academic centers who can advise when adopting new therapies in clinical practice."

This need reflects a larger issue when it comes to clinical trial design and recruitment. Staffing is considered a major reason that many practices are unable to recruit and retain patients.[8] As long as these gaps exist, oncologists will continue to struggle with the implementation of cutting-edge, lifesaving therapies. Ultimately, large, urban academic centers simply have more resources.

"Clinical trials require significant infrastructure including research coordinators, data systems, IRB [institutional review board] oversight, and regulatory expertise," said Dr. Patel. "Academic centers benefit from institutional investment distributed across departments, while community practices must build capabilities independently without adequate funding. Regulatory complexity has increased dramatically, creating additional burden that disproportionately affects smaller practices."

The Big Picture

Immunotherapy has revolutionized cancer care over the past decade. However, access to this life-saving treatment isn't equitable. Major implementation barriers, such as location, finances, and infrastructure considerations, continue to create hurdles for oncologists and patients alike. These barriers to access are reflective of the obstacles to clinical trial enrollment and retention, which makes treatments like immunotherapy possible in the first place.

Going forward, experts say oncologists from large academic centers and small rural practices need to work together to share information, educate one another on drug toxicities and use cases, and leverage technology such as virtual visits to help mitigate barriers to care. In the end, improving clinical trial access will not only help patients but also improve cancer therapy overall.

"Every cancer patient deserves access to clinical trials regardless of geography or socioeconomic status," said Dr. Patel. "Every approved therapy should be tested in populations representing its intended use. Every community practice with clinical expertise should have the opportunity to participate in advancing cancer research."

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Regulatory Actions

Regulatory approvals, designations, and guidance in the field of hematologic oncology

Scan to learn more.

March 1, 2026

Pirtobrutinib Approved in China for Relapsed or Refractory CLL or SLL

The oral Bruton's tyrosine kinase (BTK) inhibitor pirtobrutinib was approved by China's National Medical Products Administration for the treatment of relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), 3 months after its US approval.

March 5, 2026

FDA Approves Tec-Dara for Adult Patients With Relapsed or Refractory Multiple Myeloma

The FDA has approved teclistamab in combination with daratumumab hyaluronidase-fihj (tec-dara) for adult patients with relapsed or refractory multiple myeloma who have received at least one prior line of therapy. Phase 3 results showed that the combination reduced the risk of disease progression or death by 83% compared with standard of care. This is the third approval under the FDA's new National Priority Voucher pilot program, which "expedites approval of applications that address critical national health priorities," according to the organization.

March 20, 2020

FDA Approves Nivolumab Plus AVD for Previously Untreated Hodgkin's Lymphoma

The FDA has approved adding nivolumab to the chemotherapy triplet doxorubicin, vinblastine, and dacarbazine (AVD) for patients 12 years or older with previously untreated, stage 3 or 4 classical Hodgkin's lymphoma. Approval is based on results of the SWOG S1826 study, which demonstrated that the combination was more effective and better tolerated than brentuximab vedotin plus AVD.

Highlights from the **NATIONAL COMPREHENSIVE CANCER NETWORK (NCCN) ANNUAL CONFERENCE, MARCH 27–29, 2026, IN ORLANDO, FLORIDA.**

The Ongoing Search for the Optimal Frontline Treatment for *TP53*-Mutated MCL

By ***Nichole Tucker***

A key clinical question in hematologic oncology centers on whether chemoimmunotherapy still has a role in the treatment of *TP53*-mutated mantle cell lymphoma (MCL) and what constitutes optimal treatment in the frontline setting, including autologous stem cell transplant (ASCT). Although intensive chemoimmunotherapy has long held its position in this setting, its benefit appears diminished in this high-risk population, according to **Ann S. LaCasce, MD, MMSc**.[1]

Ann S. LaCasce, MD, MMSc

At the 2026 NCCN Annual Conference, Dr. LaCasce presented on new approaches to treating *TP53*-mutated MCL. For frontline treatment, three clinical trials ushered in the new era of treatment: the phase 3 TRIANGLE study, the phase 2 BOVen trial, and the phase 2 TrAVeRse study.

In the TRIANGLE study, investigators set out to discover whether the addition of ibrutinib to chemoimmunotherapy would improve outcomes and preclude the need for ASCT. The investigation included 870 patients with treatment-naive MCL.[2]

Patients were randomized 1:1:1 to group A (control) and two experimental groups: A+I and I. Group A received ASCT followed by two chemoimmunotherapy regimens (R-CHOP and R-DHAP), observation, and 3 years of rituximab maintenance. Group A+I was administered the same chemoimmunotherapy regimens after ASCT with 2 years of ibrutinib maintenance, observation, and 3 years of rituximab maintenance. In group I, patients had chemoimmunotherapy, with 2 years of ibrutinib maintenance, observation, and 3 years of rituximab maintenance.

The findings showed that ibrutinib did improve efficacy, with a median 4-year failure-free survival (FFS) rate favoring group A+I versus group A (hazard ratio [HR], 0.64; P=0.0026) and FFS also favoring group I compared with group A (P=0.0208). The added efficacy of ibrutinib was without added toxicity.

PHOTO CREDIT: istock.com/SeanPavonePhoto

TRIANGLE laid the groundwork for modern treatment of MCL by setting ibrutinib-containing chemoimmunotherapy after ASCT as a standard of care. The phase 2 BOVen trial, which was published shortly afterward, took the clinical question a step further by questioning the role of chemoimmunotherapy altogether. According to Dr. LaCasce, this was a pivotal moment in MCL research because outcomes with chemoimmunotherapy were unfavorable.

In BOVen, 25 patients with *TP53*-mutated MCL received first-line treatment consisting of zanubrutinib, obinutuzumab, and venetoclax. The regimen achieved a 2-year progression-free survival (PFS) rate of 72%. In terms of the secondary end points of the study, the combination also achieved a disease-specific survival rate of 91% and overall survival (OS) rate of 76%.[3] The PFS results did not only exceed historic PFS results for first-line MCL therapy (Nordic MCL-2 and MCL-3),[4] they also showed that patients could derive benefit from therapy without transplant.

In the phase 2 TrAVeRse study, another chemotherapy- and ASCT-free option was evaluated and showed promise, according to preliminary results.[5] A total of 108 patients with treatment-naive MCL were evaluated during treatment with acalabrutinib plus venetoclax and rituximab (AVR) in TrAVeRse. At a median follow-up of 14.9 months, the measurable residual disease (MRD) negativity rate was 76.9% at the end of cycle 3 and 88.0% at the end of cycle 6. AVR achieved a PFS rate of 97.1% and an OS rate of 98.1%. The overall response rate observed was 95.4% with a 98.0% duration of response.

Although fully validated results are pending, the study thus far has added to the growing body of evidence on optimal first-line treatment for *TP53*-mutated MCL.

Overall, the clinical question of whether chemoimmunotherapy still has a role in treating *TP53*-mutated MCL remains, but the new results show how immunotherapy and targeted therapy have potential to fill the role previously held by intensive chemoimmunotherapy. Furthermore, as a growing number of upfront trials exclude ASCT, it inadvertently answers the question of its utility in the frontline treatment of patients with MCL and *TP53* mutations.

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The Management Landscape for Relapse in Multiple Myeloma

*By **Andrew Moreno***

At the 2026 NCCN Annual Conference, **Shaji K. Kumar, MD,** of the Mayo Clinic, presented on the current state of, and practices in, intervention for relapse in multiple myeloma.[1]

Shaji K. Kumar, MD

As described by Dr. Kumar, progress in multiple myeloma treatment development has mainly been seen in newly diagnosed disease, but there have also been advances in relapsed disease over the last decade. Clinical trials are under way for intervention approaches such as immunotherapy, chimeric antigen receptor (CAR) T-cell therapies, and bispecific and trispecific antibodies to expand the options for patients who continue to experience disease relapse.

"Hopefully, that will also change as the therapies get better, and each of these remissions lasts longer and longer. Hopefully we will stop seeing some of those patients getting to those late relapses," Dr. Kumar said.

On the question of when to begin treatment for disease relapse, Dr. Kumar said having high-risk features at initial diagnosis merits immediate start of therapy, as do CRAB features, or rapidly elevated M protein levels, though a period of monitoring can be considered for some patients. Results are awaited from prospective studies on whether survival benefit is greater with start of therapy at the onset of CRAB features or at the first sign of biochemical progression.

"Until then, I think it is a combination of your sense of comfort, the patient's sense of comfort, as well as the trend in the disease parameters," Dr. Kumar stated.

Dr. Kumar reviewed important considerations to remember for treatment selection in disease relapse, highlighting that brevity of response to the initial therapy points to biologically high-risk disease, along with the significance of whether frontline therapy included stem-cell transplant, and the type of maintenance therapy received. Combination regimens are preferable to monotherapy, and that regimen should be followed through to

maximum response then followed by a single agent.

"But that paradigm could also be changing with the new therapies, particularly CAR-Ts and the bispecific antibodies," Dr. Kumar noted.

About the combination approaches to take after a first relapse, Dr. Kumar spoke of four patient cohorts; patients who are refractory to lenalidomide, to anti-CD38 monoclonal antibodies such as daratumumab, to both of these agent types, or to neither. For patients refractory to only one of the two agents, he spoke of the combination options available and the phase 3 trials supporting their use, namely the triple-agent combinations investigated in the CANDOR,[2] IKEMA,[3] APOLLO,[4] and ICARIA[5] studies.

For patients who have sensitivity to lenalidomide, Dr. Kumar's presentation listed the triplets associated with the ASPIRE, TOURMALINE, POLLUX, and ELOQUENT trials. This was followed by a listing of the proteasome inhibitor-based regimens from ENDEAVOR, CASTOR, OPTIMISMM; a randomized phase 2 study of elotuzumab plus bortezomib and dexamethasone; and the BOSTON[6] trial whose data on the selinexor-bortezomib-dexamethasone triplet he delved into later in the presentation.

"So, quite a few choices in terms of what you can pick from. But, again, everything is based on what did they get exposed to in the frontline therapy, how long did they stay on the treatment, and did they relapse on therapy or off therapy," Dr. Kumar emphasized.

"I think for those patients with high-risk disease, we still have quite a bit of challenge with many of them despite having all of these treatments."

—Shaji K. Kumar, MD, The Mark and Judy Mullins Professor of Hematologic Malignancies and Research Chair for the Division of Hematology, Mayo Clinic

According to Dr. Kumar, among the most important clinical trial data to be released in the last year and a half were findings from the phase 3 MajesTEC-3 trial,[7] where teclistamab plus daratumumab showed impressive survival results in multiple myeloma with one to three prior lines of treatment. Regarding CAR T-cell therapy options for early relapses, he spoke of the CARTITUDE-4[8] and KarMMa 3[9] trials, which, respectively, compared ciltacabtagene autoleucel (cilta-cel) and idecabtagene vicleucel (ide-cel) with standard of care.

While pointing out that the two trials' data were not comparable and that there has not been a head-to-head trial of these CAR T-cell therapies, Dr. Kumar remarked that "real-world studies that have been done through consortia clearly show that cilta-cel is associated with a deeper response and more durable response compared to ide-cel. Most of what we use in the clinic now is cilta-cel."

On the BCMA-targeted antibody drug conjugate belantamab mafodotin, Dr. Kumar reviewed data from the phase 3 DREAMM-7[10] and DREAMM-8[11] trials. He said that although ocular toxicity remains a challenge and close monitoring is needed, these two trials showed a similar degree of benefit over standard of care with the addition of belantamab mafodotin. Moreover, each of these trials "tells us that these new drugs in combination with some of the existing drugs, clearly, can be options for these patients."

For patients who have had two, three, or more relapses, management is challenging but clinical investigations are in progress and options are expanding. Among targeted therapies are the single-agent bispecific antibodies elranatamab, linvoseltamab, and talquetamab, which all show comparable response rates. Venetoclax has also demonstrated efficacy potential in clinical trials, although it is not currently approved for use in myeloma.

Dr. Kumar mentioned other promising approaches that are under clinical trial investigation, both to treatments broadly applicable to all patients and also targeted therapies tailored to specific patients. Among these are bispecific antibody combinations, trispecific antibodies, dual-targeting and next-generation CAR T-cell therapies, and the cereblon E3 ligase modulators iberdomide and mezigdomide. Also included are small molecule agents such as BCL2 inhibitors, MMSET inhibitors, and protein degraders. Meanwhile, drug classes traditionally common in myeloma care, such as alkylating agents and anthracyclines, will continue to have importance especially within polytherapy.

During the question-and-answer session, Dr. Kumar was asked whether he expected CAR T-cell therapy to replace transplant in the treatment consolidation phase. He replied that phase 3 trials are under way to answer that question, but he expects there to be such a replacement for some patients while for others the replacement will be with a bispecific antibody combination.

"Either way, I suspect there's going to be a significant number of patients we are not going to be transplanting in the upfront setting," Dr. Kumar clarified.

During the presentation, he mentioned that autologous stem cell transplant has increasingly fallen out of favor for frontline therapy but remains an important option at first relapse. Elaborating during the question-and-answer session, he said transplant remains the standard of care in the frontline setting per phase 3 trial findings, and in his view, anyone eligible for transplant should be offered it, though it is very reasonable to delay if the patient wishes to.

"I think for those patients with high-risk disease, we still

have quite a bit of challenge with many of them despite having all of these treatments. In those patients, I would definitely more skew toward doing an early transplant until we have better readouts from some of these newer therapies," Dr. Kumar explained.

"[If] you have an option between a CAR-T and a bispecific, and both are accessible for that patient, I would go with a CAR-T therapy."

—Shaji K. Kumar, MD, The Mark and Judy Mullins Professor of Hematologic Malignancies and Research Chair for the Division of Hematology, Mayo Clinic

For patients with high-risk disease, Dr. Kumar sees little to no role for tandem transplants or allogeneic stem cell transplant and feels that in the event of a relapse between a first and possible second transplant, an intervention other than transplant should be considered. To a question of whether he feels there is any wrong sequence when using CAR T-cell therapies and bispecific antibodies, he said he does not believe there is but more must be learned from studies.

"If you are thinking about somebody in front of you, and you have an option between a CAR-T and a bispecific, and both are accessible for that patient, I would go with a CAR-T therapy," Dr. Kumar summarized.

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Personalized Antiemetic Strategies Redefine Supportive Care in Chemotherapy

*By **Nichole Tucker***

Standard-of-care (SOC) antiemetic prophylaxis for patients undergoing moderately emetogenic chemotherapy (MEC) does not fit every patient.[1] Individual risk factors common for patients with an elevated risk for chemotherapy-induced nausea and vomiting (CINV) warrant new options, and research has shown that prophylaxis with neurokinin-1 (NK1) receptor antagonist (RA)–containing therapies may improve antiemetic prophylaxis.[1]

Results from the multinational MyRisk trial showed improved antiemetic control with a NEPA-based regimen. (NEPA is a fixed combination of an NK1 RA, netupitant, and a5-hydroxytryptamine-3 RA, palonosetron). In the study, 388 patients with various cancer types receiving MEC were treated with either NEPA plus dexamethasone or SOC prophylaxis. Patients in the NEPA arm were significantly more likely to achieve a complete response (CR), defined as no emesis and no rescue medication, across cycles (odds ratio, 1.67; 95% CI, 1.12-2.49; $P=0.012$). The probability of CR reached 81.0% with NEPA plus dexamethasone compared with 71.8% with standard therapy.

Additional efficacy measures favored the three-drug approach. The likelihood of experiencing no nausea was 63.7% with NEPA versus 54.9% with standard prophylaxis. Rates of no emesis were also higher, at 95.4% compared with 86.7%. Complete protection, which includes no emesis, no rescue therapy, and no significant nausea, was achieved in 71.8% of patients in the NEPA group versus 62.4% in the SOC group.

According to study co-investigator, **Eric J. Roeland, MD,** of Oregon Health and Science University who spoke with *Blood Cancers Today* about MyRisk, the findings show substantive gains for the NEPA-containing regimen.

Eric J. Roeland, MD

"These gains meaningfully reduce CINV burden, optimize supportive care delivery, minimize avoidable toxicity and patient time costs, and support consistent antineoplastic treatment," Dr. Roeland stated. "The benefit was driven largely by better control in the delayed phase (25 to 120 hours) and higher rates of no nausea and complete protection—translating into fewer breakthrough events, less use of rescue medications, and measurable improvements in daily functioning. By preventing recurrent CINV up front, personalized escalation can reduce unscheduled patient contacts and the cumulative time patients and caregivers spend seeking symptomatic care while preserving antineoplastic therapy delivery."

Ultimately, MyRisk reinforces prior research predictions that the SOC doublet is insufficient for many patients with cancers requiring antiemetic prophylaxis, according to Dr. Roeland and colleagues. At the same time, the findings reveal the need for a more personalized approach to antiemetic prophylaxis, which may be determined based on patient-specific risk factors in the MEC setting.

"Incorporating patient-level predictors like age, expectation of nausea, prior CINV, history of morning sickness, platinum/anthracycline exposure, prior nonprescribed antiemetic use, [and] cycle number shifts practice from chemotherapy-centric to personalized prophylaxis—prompting upfront NK1 receptor antagonist inclusion or use of long-acting fixed combos like NEPA in those scoring high, rather than reactive, escalation after breakthrough nausea and vomiting. It also focuses on anticipatory management and guides agent choice toward pharmacology matched to delayed-phase risk and regimens that simplify adherence," Dr. Roeland said.

MyRisk represents the first prospective effort to use pretreatment risk factors to guide patient selection among those receiving MEC. The evidence could be practice-changing, investigators note, but personalizing risk-adapted antiemetic strategies in CINV management requires implementation in clinical practice, especially for smaller centers.

Dr. Roeland explained this, noting considerations that could influence adoption of the personalized antiemetic prophylaxis strategy.

"Uptake of risk-adapted antiemetic strategies will depend on guideline endorsement, cost/reimbursement and formulary coverage for NK1 receptor antagonist regimens, demonstration of health-economic value (fewer ED [emergency department] visits, preserved dose intensity), integration of an easy risk tool into clinical workflows and electronic medical records, clinician and patient education to change prescribing behavior, and validation across diverse regimens (including ADCs [antibody-drug conjugates]) and populations to ensure generalizability and equitable implementation," said Dr. Roeland.

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PARADIGM AML Trial Update: Azacitidine Plus Venetoclax Shows Superiority to SOC Chemotherapy

*By **Andrew Moreno***

Amir Fathi, MD

The PARADIGM phase 2 prospective study, which concerns fit adult patients with newly diagnosed acute myeloid leukemia (AML), evaluated azacitidine plus venetoclax against two types of intensive induction chemotherapy, the current standard of care. Survival data are still maturing, but the doublet therapy has so far shown superior efficacy in a study update presented at the 67th American Society of Hematology Annual Meeting & Exposition.

"Aza-ven [azacitidine plus venetoclax] led to numerically fewer serious infectious complications, significantly improved QOL [quality of life] and symptom burden during initial therapy, with less time in the hospital and the ICU," noted first author **Amir Fathi, MD,** of Massachusetts General Hospital and Harvard Medical School, Boston, and colleagues.

The total cohort in this randomized, open-label clinical trial was 172 patients from nine US centers. All were aged 18 years and older and eligible for induction chemotherapy. None had core binding factor fusions or *FLT3* mutations, and *NPM1* mutations were permitted only in patients aged 60 years or older.

The study combination, azacitidine plus venetoclax, was administered to 86 patients of the total cohort. In this study arm, the median age was 64 years, 55% of patients were men, 65% were White, and the median number of completed treatment cycles was four. The induction chemotherapy study arm included 86 patients with a median age of 65 years; 60% were men, and 69% were White. In this arm, 54% of patients received induction chemotherapy with the 7+3 regimen, and 46% received liposomal daunorubicin plus cytarabine; the median number of completed treatment cycles was two.

The investigators noted that in the total cohort, European LeukemiaNet 2022 risk was adverse in 72% of patients, intermediate in 15%, and favorable in 12%, and that this risk distribution did not differ between the two study arms (P=0.44). These arms also had comparable proportions of *IDH1/2, NPM1,* and *TP53* mutations.

At 2 weeks, the study combination showed superiority over the two induction chemotherapies in patients' reported QOL (P=0.001), symptom burden (P=0.019), and depression symptom (P=0.007) scores. In the study combination arm, there was 0% ICU care need versus 9.8% in the induction chemotherapy arm (P=0.003), the number of inpatient days at index hospitalization was 15 versus 36 (P<0.001), respectively, and during the first 6 months was 41 versus 58 (P<0.001), respectively.

The median follow-up in the intent-to-treat analysis was 16 months. In the study combination and induction chemotherapy arms, the overall response rate was 88% versus 62% (P<0.001), the composite remission rate was 81% versus 55% (P<0.001), the rate of advance to transplant following therapy response was 61% versus 40% (P=0.009), and the 1-year event-free survival (EFS) rate was 53% versus 39%.

The two arms had similar profiles of grade 3 or 4 therapy-related adverse events that affected 10% or more of their patients, and in both arms, most such events were hematologic. Grade 3 or 4 lung infections occurred in 12% of patients in the combination arm and 15% in the induction chemotherapy arm, and sepsis occurred in 7% of patients in the combination arm and 11% in the induction chemotherapy arm. Thirty-day mortality was 0% in the combination arm and 3.5% in the induction chemotherapy arm, and 60-day mortality was 0% in the combination arm and 4.7% in the induction chemotherapy arm.

"[T]he era of intensive induction chemotherapy may be passing for certain subsets of AML, such as for those transplant-eligible patients with intermediate- or adverse-risk, *FLT3* wild-type disease."

—Amir Fathi, MD, Professor of Medicine, Harvard Medical School

In written comments forwarded to *Blood Cancers Today,* Dr. Fathi remarked based on the trial's findings that "[t]he era of intensive induction chemotherapy may be passing for certain subsets of AML, such as for those transplant-eligible patients with intermediate- or adverse-risk, *FLT3* wild-type disease." He summarized that "among fit adult AML patients with these molecular risk features, when compared to intensive induction, azacitidine and venetoclax led to a higher composite remission rate, improved EFS, similar OS [overall survival], more transition to allogeneic transplant, briefer hospitalization, less high graded bleeding and hemorrhagic events, and improved quality of life measures and patient-reported outcomes."

REFERENCE

1. 67th American Society of Hematology Annual Meeting & Exposition. Abstract No. abs25-8236.

First Chemotherapy-Free Immunotherapy Regimen Achieves Durable Responses in Waldenström's Lymphoma

*By **Melissa Badamo***

ImmunityBio's off-the-shelf, allogeneic CD19 chimeric antigen receptor (CAR) natural killer cell therapy (CD-19 t-haNK) achieved durable complete response rates in combination with rituximab in patients with Waldenström's non-Hodgkin's lymphoma, according to updated results from the ongoing QUILT-106 trial.[1]

The open-label, first-in-human, phase 1 study enrolled four patients who did not respond to standard-of-care therapy,[1] with plans to enroll up to 10 patients.[2] To combine CD19 and CD20 immunotherapies for optimal tumor targeting, the researchers infused CD19 CAR NK cells with rituximab. In total, patients received eight doses of cell therapy without lymphodepletion and six doses of rituximab in the outpatient setting.[1]

Complete responses stretched into 7 and 15 months for two evaluable patients, respectively, with all four patients achieving 100% disease control. Researchers observed complete responses after four doses of cell therapy, and one patient with 95% bone marrow infiltration by tumor cells at baseline achieved complete bone morphologic remission after therapy.[1]

"This updated follow-up reinforces the central thesis that restoring and activating the immune system can deliver durable control of disease without chemotherapy or lymphodepletion," said **Patrick Soon-Shiong, MD,** founder, executive chairman, and global chief medical and scientific officer of ImmunityBio, in a press release.[1]

These findings build on results presented at the 67th American Society of Hematology Annual Meeting & Exposition by **Jacqueline Thomson, MD,** of the Donald Gordan Medical Center in Johannesburg, South Africa. Dr. Thomson and colleagues did not observe any significant toxicities, cytokine release syndrome, dose-limiting toxicities, or unexpected immune adverse events with CD19 t-haNK monotherapy or CD19 t-haNK in combination with rituximab.[3]

Jacqueline Thomson, MD

Enrollment and follow-up are currently ongoing, with further clinical updates expected once efficacy and safety data mature. Furthermore, researchers are designing a follow-up study of CD-19 t-haNK in combination with rituximab and nogapendekin alfa inbakicept (N-803), an interleukin-15 superagonist.[1]

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2. ClinicalTrials.Gov. ID: NCT06334991. Accessed February 9, 2026. https://clinicaltrials.gov/study/NCT06334991
3. 67th American Society of Hematology Annual Meeting & Exposition. Abstract No. 25-13885.

Calendar

April 29–May 2
2026 American Society of Pediatric Hematology/Oncology (ASPHO) Conference
Minneapolis, MN

May 29–June 2
2026 American Society of Clinical Oncology (ASCO) Annual Meeting
Chicago, IL

June 8–9
22nd Global Summit on Hematology and Blood Disorders
Dubai, UAE

June 11–14
European Hematology Association (EHA) 2026 Congress
Stockholm, Sweden

June 24–27
American Association for Cancer Research (AACR) Advances in Malignant Lymphoma
Philadelphia, PA

June 26–27
Mayo Clinic Updates in Hematology and Oncology
Montreal, Canada

July 23–26
Debates and Didactics in Hematology and Oncology
Sea Island, GA

September 9–12
Society of Hematologic Oncology (SOHO) Fourteenth Annual Meeting
Houston, TX

September 23–26
23rd International Myeloma Society (IMS) Annual Meeting
Glasgow, Scotland

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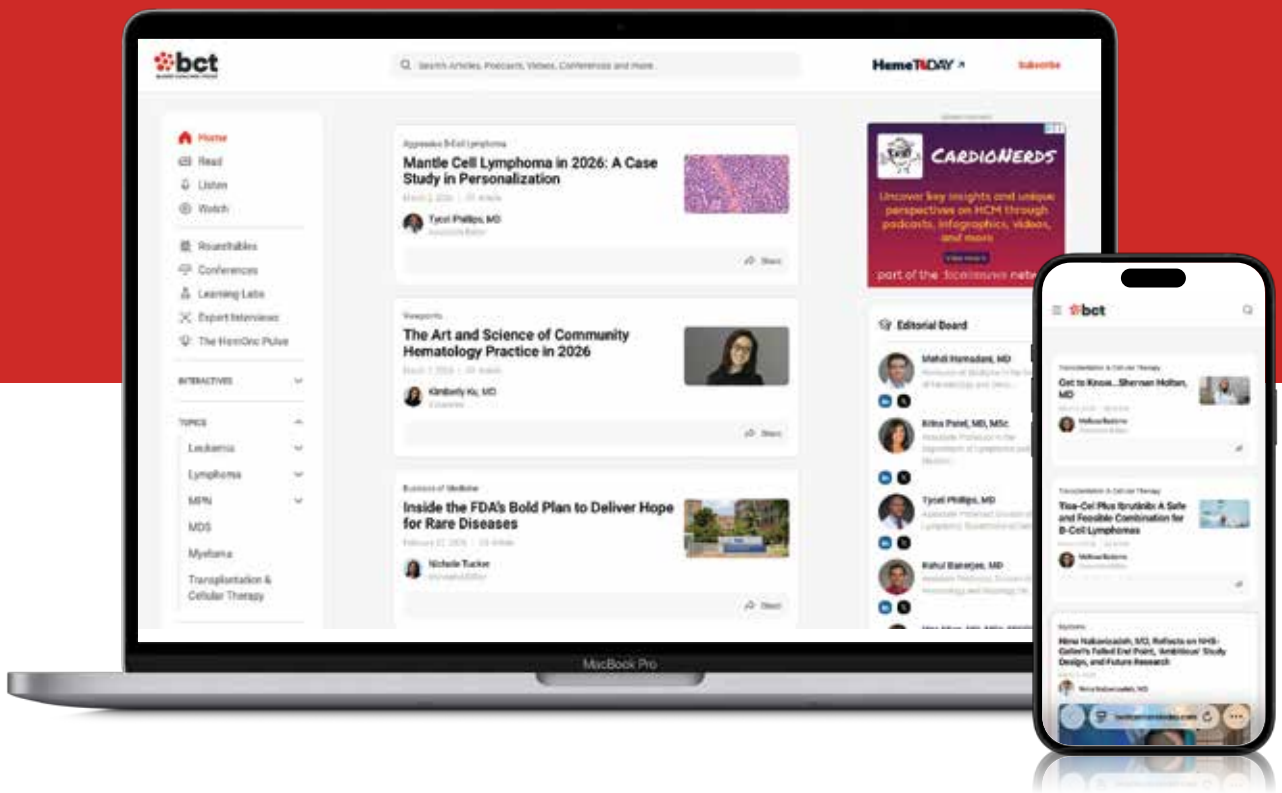

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Editor's Picks

In each issue of Blood Cancers Today, *we will take a closer look at a particular topic in hematologic malignancies. This month, associate editor* ***Amer Zeidan, MBBS, MHS,*** *Professor of Medicine (Hematology) at Yale School of Medicine, highlights recent research in acute myeloid leukemia (AML) in honor of AML World Awareness Day on April 21.*

Visit bloodcancerstoday.com to stay up to date on the latest news in each area of hematologic oncology.

Amer Zeidan, MBBS, MHS

ACUTE MYELOID LEUKEMIA

New Prognostic Clues for Ruxolitinib Plus Venetoclax in Relapsed or Refractory AML

By ***Andrew Moreno***

A phase 1 multicenter clinical trial of ruxolitinib plus venetoclax for adults with relapsed or refractory acute myeloid leukemia (AML) was conducted. The researchers, led by **Uma Borate, MBBS,** of The Ohio State University Comprehensive Cancer Center in Columbus, found this novel all-oral combination to be safe in the patient population and identified possible biomarkers for response to this doublet.

Uma Borate, MBBS

Their study findings were published in *Blood Neoplasia*. Dr. Borate and colleagues found that treatment with the combination "in R/R [relapsed or refractory] or in HMA [hypomethylating agent]–exposed, intensive chemo-ineligible secondary AML is well tolerated with moderate efficacy, particularly in CD56-negative patients and those with prior MDS [myelodysplastic syndromes] and/or an underlying *JAK2* mutation (who typically have poor response to cytotoxic chemotherapy)."

"This is the first study combining these two drugs in myeloid malignancies at various doses ... we are expanding the study based on these results to a triplet of Aza+Ven+Rux in R/R AML patients."

—Uma Borate, MBBS, Associate Professor, The Ohio State University Comprehensive Cancer Center

"This is the first study combining these two drugs in myeloid malignancies at various doses," Dr. Borate noted in additional written remarks provided to *Heme Today*, affiliate publication of *Blood Cancers Today*.

The cohort included 30 patients with a median age of 69 years; 40% had received at least three prior lines of therapy, and in 43%, a prior venetoclax intervention was unsuccessful. They received two cycles of twice-daily oral ruxolitinib (30 mg) and daily oral venetoclax (400 mg), which from this trial, the researchers identified as the recommended phase 2 dose.

The cohort received the study combination for a median duration of 55 days. The doublet was well tolerated, and no dose-limiting toxicities were encountered. The patients had a clinical response rate of 20% and a composite complete remission rate of 10%. The median survival in the cohort was 3.7 months, and 23% of patients remained alive at 1 year after receiving the combination. Among the responding patients were two, both with secondary AML, who continued the treatment for 14 and 49 months, respectively.

This phase 1 trial also provided the researchers with clues to biomarkers for predicting response to the study doublet. Most prominent among these, patients with greater blast CD56 expression before the study treatment were markedly less likely to have a clinical response and had shorter survival.

"In an effort to eventually move this combination to the frontline setting, especially for CD56 negative AML patients, we plan to add HMA to Rux+Ven [ruxolitinib plus venetoclax] for treating R/R patients to see if CD56 expression still predicts clinical outcomes and if the addition of HMA enhances response," Dr. Borate and colleagues wrote in their published findings. Namely, Dr. Borate told *Heme Today,* "We are expanding the study based on these results to a triplet of Aza+Ven+Rux [azacitidine plus venetoclax plus ruxolitinib] in R/R AML patients."

There were other potential prognostic biomarker findings of interest. The researchers observed, in a subset of patients, that pCREB upregulation and CD11b downregulation in primary cells by day 8 of the treatment were associated with nonresponse to the doublet. They also found that if the proteins involved in mitochondrial dynamics diminished in a patient within the first week of treatment, this was ultimately associated with a response to the doublet. A rise in these proteins, conversely, was associated with nonresponse. Patients who ultimately responded to the treatment were also found to have increased expression of *PI3K/AKT* pathway genes before treatment.

REFERENCE

Borate U, et al. *Blood Neoplasia.* 2026;100205. doi:https://doi.org/10.1016/j.bneo.2026.100205

Venetoclax Plus HAM Shows High Remission Rates in Relapsed AML

*By **Dean Patterson***

The prognosis for patients with relapsed or refractory acute myeloid leukemia (AML) has long been poor, with conventional salvage regimens delivering modest remission rates and short survival. In that context, the RELAX trial—led by **Christoph Röllig, MD, MSc,** of University Hospital Carl Gustav Carus, Dresden, Germany, and published in *The Lancet Haematology*—takes a closer look at whether adding venetoclax to a familiar intensive backbone might move the needle.

Christoph Röllig, MD, MSc

This was a multicenter, open-label, phase 1/2 study conducted across 12 German centers that enrolled 55 adults aged 18 to 75 years who were considered fit for intensive chemotherapy. The cohort reflects real-world complexity: nearly half had adverse-risk disease by European Leukemia Network 2022 criteria, over one-third had already undergone allogeneic transplant, and most were being treated for relapsed—not primary refractory—disease.

The regimen itself is straightforward in concept but intensive in execution. Patients received venetoclax at 400 mg daily for 14 days (with a ramp-up), layered onto high-dose cytarabine and mitoxantrone (HAM). Dose escalation in phase 1 never identified a maximum tolerated dose, and the highest cytarabine dose tested was carried forward into phase 2. That alone is notable; there was no clear signal that venetoclax compounded toxicity beyond what clinicians already expect from HAM.

Where things get interesting is the response data. The composite complete remission rate came in at 75%, which stands out against historical benchmarks closer to 50% with cytarabine-based salvage alone. Responses weren't evenly distributed, though. Patients with de novo AML had much higher remission rates than those with secondary or therapy-related disease. Still, even in a mixed-risk population, that overall signal is hard to ignore.

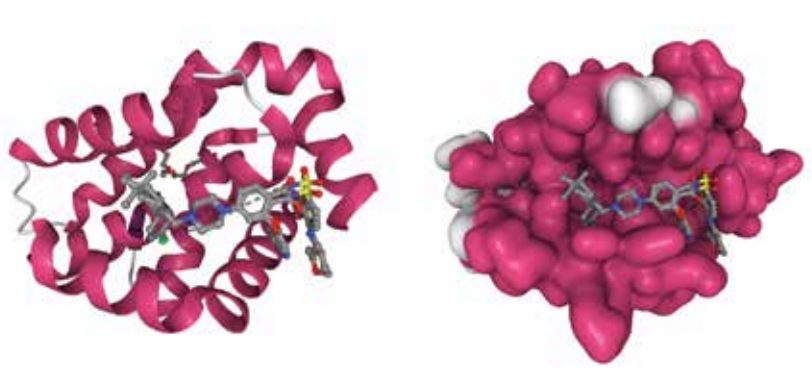
Depth of response was more variable. Measurable residual disease negativity, depending on how it was measured, ranged from roughly a quarter of patients by flow cytometry to just over 40% using molecular assays. That's not unprecedented, but it does leave open the question of how durable these remissions are without transplant consolidation.

And that's really where this regimen seems to earn its place. Among those who achieved remission, the majority—close to 90%—went on to allogeneic transplant, typically within 2 months. In practice, that's what many clinicians are trying to accomplish in this setting: get the disease under control quickly enough to bridge to transplant.

Follow-up, at a median of just over 30 months, suggests that some of these responses hold. Median overall survival wasn't reached, and about half the patients were still alive at 2 years. Relapse-free survival tracked in a similar range. For relapsed AML, those numbers are better than what most would expect from chemotherapy alone.

Infections, unsurprisingly, dominated toxicity. Febrile neutropenia occurred in more than half of patients, and both pneumonia and sepsis were reported in about one in five. There were four treatment-related deaths, all linked to infectious complications. That said, early mortality at 30 days was 6%, which compares reasonably with other intensive salvage approaches.

Some patterns emerge in the subgroup data. Patients with *NPM1* or *IDH1/2* mutations appeared to do better, while those with *TP53* alterations or complex cytogenetics fared worse. Again, not unexpected, but it reinforces how much underlying biology still drives outcomes even with newer combinations.



A few questions linger. Is HAM plus venetoclax the best backbone for this strategy, or would FLAG-IDA–based combinations yield deeper remissions? And for patients who can't proceed immediately to transplant, is there a defined role for venetoclax maintenance, or are we still feeling our way there?

Even with those uncertainties, RELAX adds something concrete to the conversation. It shows that venetoclax can be paired with intensive chemotherapy in this setting without prohibitive toxicity, and that doing so may give more patients a real shot at transplant.

REFERENCE

Ruhnke L, et al. *Lancet Haematol.* 2026;13:e157-e168. doi:10.1016/S2352-3026(25)00358-8

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ASPHO Awards Highlight Childhood Cancer Survivorship and Genomics

At the American Society of Pediatric Hematology/Oncology (ASPHO) Annual Meeting, two experts will be honored for their contributions to the field of pediatric oncology. The conference will take place April 29 to May 2, 2026, in Minneapolis, Minnesota.

*By **Melissa Badamo***

Childhood Cancer Survivorship Award for Excellence


Karen Effinger, MD, MS

As the daughter of a nursing administrator, **Karen Effinger, MD, MS,** grew up in the world of healthcare. She volunteered at a children's hospital and developed an interest in oncology after experiences with cancer in her family. Although she majored in history in college, she also pursued a pre-med track and ultimately circled back to her passion—pediatric oncology.

"It was the intersection of forming long-term relationships with patients and taking care of them in the acute setting that kept pulling me into pediatric oncology," Dr. Effinger told *Blood Cancers Today* in an interview. She currently serves as a pediatric oncologist and associate professor in the Department of Pediatrics at Emory University School of Medicine in Atlanta, Georgia.

Now, more than a decade into her career, Dr. Effinger has received the 2026 ASPHO Childhood Cancer Survivorship Award for Excellence, which is funded by Northwestern Mutual. Each year, the award is granted to a mid-career investigator who displays commitment to pediatric cancer survivorship research and project funding.

"Receiving the Northwestern Mutual ASPHO Survivorship Excellence Award is a great honor. It's an area in oncology that isn't often highlighted, so having an award that highlights this work is very special," Dr. Effinger said.

The award also includes a $10,000 honorarium to support Dr. Effinger's research, which focuses on the late physical and psychosocial effects of childhood cancer treatment. Dr. Effinger aims to improve outcomes for pediatric and adolescent patients with a specific focus on improving health behaviors, nutrition, and exercise while preventing substance use and abuse. She is currently working to optimize the transition period for adolescents and young adults as they move from pediatric centers to adult centers and care delivery.

"I'm hoping to use some of the funding to help improve abstracting information from medical records to digitize our survivorship care plans," she explained.

Survivorship plans are curated for each patient. They include a summary of a patient's treatment and a link to the Children's Oncology Group long-term follow-up guidelines, which provide a roadmap of long-term screening and surveillance that can catch late effects of cancer treatment early.

"Right now, it's very time consuming with a lot of errors. We're trying to use AI [artificial intelligence], large language models, and other computational techniques to semi-automate them," Dr. Effinger added.

Dr. Effinger is also part of a joint cardio-oncology initiative between Children's Healthcare of Atlanta's Sibley Heart Center and Survivorship Clinic to prevent and monitor cardiotoxicity among adolescent and young adult patients. Through this partnership, Dr. Effinger and her team develop guidelines to determine which patients should be referred to cardiology based on risk status, how to adopt measures to detect early cardiotoxicity, and how to ensure that patients who receive cardiotoxic medications maintain heart health and safely participate in sports.

In the next 5 to 10 years, Dr. Effinger hopes to see novel medications to prevent late effects, more advocacy and government support, more protection for cancer survivors, and better insurance coverage to ensure that patients can afford cancer screenings. Importantly, she also hopes to extend her survivorship efforts into young adult and adult patients.

"I hope to continue to see a greater recognition of the importance of survivorship," she added. "There's a lot that we have learned that can be extended into places that haven't had as much reach. There is a growing hope that as we learn more about genetics and what places patients at risk, we will do a better job of tailoring therapy up front and developing new medications."

George R. Buchanan Lectureship Award

Kim Nichols, MD, began her pediatric hematology oncology fellowship at Boston Children's Hospital and the Dana-Farber Cancer Institute in 1992, where she worked in a genetics lab researching hereditary predisposition to childhood cancer. Back then, the field was just beginning to develop.


Kim Nichols, MD

"When I was a fellow, I was surrounded by all this emerging knowledge about hereditary predisposition to cancer. I thought maybe I could begin to work in this field," said Dr. Nichols, who is the director of the Cancer Predisposition Division at St. Jude Children's Research Hospital in Memphis, Tennessee.

Flash forward to 2026, Dr. Nichols is the recipient of this year's ASPHO George R. Buchanan Lectureship Award. Named after a leading specialist in pediatric hematology oncology, the award is

granted to a nationally or internationally recognized expert and committed mentor with research, education, and clinical expertise.

"This award is a tremendous honor. It came as a complete surprise," Dr. Nichols said. "The fact that it's named after Dr. Buchanan makes it extra special. I only met Dr. Buchanan once, but he made such a large impression on me. His kindness and knowledge are deep, and he is truly committed as a mentor who wants to see his trainees succeed."

Dr. Nichols will present an overview of her research at the ASPHO meeting, which focuses on identifying novel genetic causes of childhood cancer and translating this information into the pediatric oncology clinical setting.

"Genetic predisposition is now permeating the pediatric oncology clinical space. It's so rewarding to see how we are using germline information to guide cancer treatment and surveillance to improve the outcomes of affected children and their families," she said.

After completing her fellowship and serving as an instructor in Boston, Dr. Nichols moved to the Children's Hospital of Philadelphia in 1999. There, she developed a flourishing pediatric cancer predisposition program and translated that success to St. Jude in 2014 by hiring a team of genetic counselors, providers, and research assistants.

"My greatest accomplishment has been to surround myself with diverse individuals, each of whom brings their own strengths to the table," Dr. Nichols said. "Together, we have created a cancer predisposition program that serves as a model to others around the world and one that can foster the next generation of cancer predisposition experts."

Dr. Nichols has also stepped into a mentorship role for younger physicians. She cites Drs. Brice Weinberg and Gary Koretzky as "tremendous" mentors during medical school and fellowship, respectively. "We're going to need to train our younger colleagues so they can continue to move the field forward," she said. "I work closely with my students and junior faculty so that they can acquire the skills needed to flourish personally and professionally in academia or whatever area that they choose. I want to find people who have a fire in their belly—people who are really excited about what they're doing."

Moving forward, Dr. Nichols hopes to see a cure for all children with cancers, especially for patients with relapsed or refractory cancers and those in lower- and middle-income countries where the cure rate is only 20% to 30%. Understanding the germline genetic factors that increase cancer risk is one piece of the puzzle that could make this vision a reality.

"St. Jude's mission is to cure as many children with catastrophic diseases, including cancer, as possible. We still have a way to go to further push the boundaries of a cure," Dr. Nichols said. "The good news about pediatric oncology is that we can cure eight out of nine children. For the few that you can't cure, it's a motivating factor to keep trying."

PaceDay Campaign Raises $366,217 for Cancer Research at Georgia Cancer Center

*By **Melissa Badamo***

Since 2019, Paceline has raised over $2 million for research at the Georgia Cancer Center through their PaceDay campaign, a community-based fundraiser that brings together cyclists, walkers, and runners to raise money for cancer research.

After a successful PaceDay 2025 campaign, Paceline presented a check for $366,217 to **Jorge Cortes, MD,** director of the Georgia Cancer Center, to fund research across various cancer types. The nonprofit organization allocates 100% of funds to the Georgia Cancer Center.

"This is a very important event," Dr. Cortes told *Blood Cancers Today*. "I see it as having three major functions. One is fundraising. The second is increasing awareness about cancer and the role that physical activity plays in decreasing the risk of cancer. The third is community. It's an opportunity to be out there with your neighbors, friends, and people you've never met before. It has been fantastic."

What began as a cycling fundraiser has now expanded to include running and walking. Although Dr. Cortes is an avid runner, he participates as a cyclist in the campaign each year. Despite obstacles such as the COVID-19 pandemic in 2020 and Hurricane Helene in 2024, the fundraiser keeps growing, with the highest number of participants recorded in 2025.

"A lot of the grants are for basic research, but we also allocate some for population health research and epidemiologic research, which is important," said Dr. Cortes. "We allocate some for early career investigators because they have particular challenges to try to get their grants. With these grants, they can generate preliminary data to apply for bigger grants from the NIH [National Institutes of Health]."

Sean Hu, PhD, an assistant professor of biochemistry and molecular biology at Georgia Cancer Center, received a young investigator grant for his research on identifying new ways to treat chronic myeloid leukemia and a specific subtype of acute myeloid leukemia.

"He is identifying a potential immune mechanism that could potentially eradicate the disease so that more patients can effectively stop therapy and we could call them cured," Dr. Cortes said.

Outside of blood cancers, the Paceline grants have funded research in breast cancer, brain cancer, and colon cancer. The next PaceDay campaign is slated for October 4, 2026, with over $10,000 raised as of March 2026 towards its $500,000 goal.

REFERENCE

Paceline. Accessed Online March 20, 2026. https://paceline.org/PaceDay2026

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figure1

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