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**LEUKEMIA/
LYMPHOMA**

SPECIAL ISSUE
09.2023

DLBCL

New advancements in treatment have been practice-changing.

'THIS IS MY LIFE'

How Mike Peters of The Alarm turned his CLL journey into a new album.

PALLIATIVE CARE

The link between Medicaid expansion and early care for patients with advanced cancers.

ON THE LOOKOUT

**Why Minimal Residual Disease Testing
Has Become the Gold Standard for Many
Patients and Providers**



For adult patients with CLL

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 - pink or brown urine
 - unexpected bleeding, or bleeding that is severe or you cannot control
 - vomit blood or vomit that looks like coffee grounds
 - cough up blood or blood clots
 - increased bruising
 - dizziness
 - weakness
 - confusion
 - change in speech
 - headache that lasts a long time

- **Infections** that can be serious and may lead to death. Tell your healthcare provider right away if you have fever, chills, or flu-like symptoms.
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 - feel lightheaded or dizzy
 - pass out (faint)
 - shortness of breath
 - chest discomfort

The most common side effects of BRUKINSA include:

- decreased white blood cell count
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- upper respiratory tract infection
- muscle, bone, or joint pain

These are not all the possible side effects of BRUKINSA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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It is not known if BRUKINSA is safe and effective in children.

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'Pivotal' Time for DLBCL Treatment Options

THERE ARE RAPID ADVANCEMENTS happening regarding treatment options for patients with diffuse large B-cell lymphoma (DLBCL). The Food and Drug Administration, in a flurry of activity, approved three new medications across a three-month period earlier this year. In this special issue of *CURE*, we are taking a close look at the new frontier of treatments for DLBCL.

"I do believe things are looking really good for patients with DLBCL," Dr. Manali Kamdar, a clinical researcher in the field of blood cancers at the University of Colorado Anschutz Medical Campus, tells us.

Kamdar describes 2022 and 2023 as "pivotal in terms of having more medications approved for patients with large-cell lymphoma."

Elsewhere in this issue, we speak with acclaimed singer-songwriter Mike Peters of Welsh rock band The Alarm. Peters wrote "Forwards," his band's latest album, while hospitalized for chronic lymphocytic leukemia.

"I thought (that) I might not come out of this place," Peters said. "That plays on your mind quite a lot. You try to be positive about it all and suppress those darker thoughts, but they come out in the music. They just do. I think your optimism comes out stronger than your pessimism — for me it does, anyway."

Also in this issue, we look at the history and potential benefits of minimal residual disease testing and offer insight from the Leukemia & Lymphoma Society regarding how patients can go about seeking the best treatment choices available and explore their options when it comes to enrolling in a clinical trial.

As always, we hope you find our stories inspirational and informative. Thank you for reading. 📖

MIKE HENNESSY JR.

President & CEO
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Debu Tripathy, M.D.

Vice President, Content
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Associate Editorial Director
Darlene Dobkowski;
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Assistant Managing Editors
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Assistant Editors
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Emily Hakkinen

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Director, National Accounts
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Veronica Boyland, Ethan Gutzlaff

Associate Director, Strategic Alliance Partnerships
Brooke Weinstein

Director, Marketing
Melissa Hindle

Group Coordinator
Samantha Melassanos

OPERATIONS & FINANCE

Circulation Director
Jon Severn; subscribe@curetoday.com, circulation@mjhassoc.com

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Leah Babitz, CPA

Controller Katherine Wyckoff

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2 Clarke Drive, Suite 100
Cranbury, N.J. 08512
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Minimal Residual Disease Remains An Evolving and Game-Changing Field


IT'S BEEN MORE THAN 20 years since treatment for patients with leukemia led the way in the development of testing for minimal residual disease, also referred to as measurable residual disease (MRD). It was pretty clear then that the key to detecting very small amounts of tumor revolved around the tumor's DNA. That is because DNA is made of two chains of complementary base pairs, and these can be multiplied and expanded either naturally (when cells divide) or artificially in a test tube using a process called polymerase chain reaction that uses some of the enzymes that are required in nature. If one or more mutations of the tumor are known, these assays for tumor-specific RNA or DNA are ultrasensitive.

MRD testing began among patients with chronic myeloid leukemia, a disease that lends itself to gauging MRD because it is driven by a specific genetic mutation, the BCR-ABL fusion, which is part of the Philadelphia chromosome that can be viewed under a microscope. It became very useful when newer drugs became available that target the abnormal growth-promoting enzyme (kinase) encoded by this mutation. As our knowledge has grown regarding

mutations in other hematological cancers that are being targeted by a growing array of drugs, MRD assays can detect not only relapse at its earliest stage but also what new mutations are evolving that lead to resistance and can be addressed by switching to the appropriate new drug.

In this special issue of *CURE* dedicated to issues facing patients with leukemia and lymphoma, we take a look at the history of MRD testing, talk with experts about its benefits for patients during their cancer journey and discuss how this technique may benefit more patients in the future.

"[MRD testing is] really the future for guiding the very best therapies," one doctor told *CURE*. "Over and over again, we've seen examples of how MRD is the best predictor for outcome and (how) it can help us know when to increase or decrease or change therapies."

In the future, more and more diseases will be managed in a more timely, precise manner with these technologies. 




DEBU TRIPATHY, M.D.
EDITOR-IN-CHIEF
Professor of Medicine
Chair, Department of Breast Medical Oncology
The University of Texas MD Anderson
Cancer Center

OUR CONTRIBUTORS IN THIS ISSUE

Contributing Writer Andy Polhamus

Contributing Photographers Andrew Jordan; Mike Kitada; Neyssa Lee

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MEDICAID EXPANSION May Explain Increased Palliative Care Use

Patients with advanced cancers, including non-Hodgkin lymphoma, who live in states that expanded Medicaid were more likely to receive early palliative care, although utilization remains low in the U.S. *By DARLENE DOBKOWSKI, M.A.*

MORE PATIENTS WITH ADVANCED cancers — including pancreatic, colorectal, lung, head and neck, and non-Hodgkin lymphoma — received palliative care services, which may be a result of Medicaid expansion under the Patient Protection and Affordable Care Act, recent study findings demonstrated.

“Our findings are encouraging, especially with growing evidence of the important benefits of palliative care for patients with cancer,” Dr. Xuesong Han, lead author of the study and scientific director of health services research at the American Cancer Society, said in a news release from the organization. “It’s imperative to know how to target ways to increase access to these services, as use, overall, remains low in the U.S.”

According to the National Cancer Institute, palliative care aims to improve quality of life and reduce pain for patients with cancer. This can include therapies to shrink, remove

or slow growth of a tumor that may be causing pain, in addition to caregiver and family support.

“The goal of palliative care is to prevent or treat, as early as possible, the symptoms of the disease and the side effects caused by treatment of the disease. It also attends to the psychological, social and spiritual problems caused by the disease or its treatment,” according to the National Cancer Institute’s Dictionary of Cancer Terms.

Researchers noted in the study, published in the journal *Health Affairs*, that although clinical guidelines have endorsed the use of early palliative care in patients with advanced cancer, its utilization has been low in the United States. The study focused on assessing the potential link between Medicaid expansion under the Affordable Care Act and palliative care utilization in patients who recently received an advanced-stage cancer diagnosis.

The rate at which patients received early palliative care (part of their first-course treatment) increased from 17% to 18.9% in states that expanded Medicaid. This also increased from 15.7% to 16.7% in states that did not expand the program. To date, 40 states and the District of Columbia have adopted the Medicaid expansion.

“These study results suggest that the expansion of Medicaid coverage may increase palliative care use,” Han said. “They also point to a potentially widening geographic disparity in receipt of guideline-recommended palliative care between states with different health policies regarding income-based Medicaid eligibility requirements.”

The increase in palliative care utilization in Medicaid-expanded states was greatest in patients with advanced colorectal, pancreatic, oral cavity and pharynx, and lung cancers, in addition to non-Hodgkin lymphoma. “Research continues to underscore the impact increasing access to comprehensive, affordable health insurance through Medicaid has on (survival of patients with cancer) and the further importance of providing greater access to palliative care services to those positive outcomes,” Lisa Lacasse, president of the American Cancer Society Cancer Action Network, said in the release. The network has been an advocate for legislation focused on palliative care access, according to the release, and continues to do so for patients at any age or stage of their diagnosis.

“To fully improve patient quality of life, Congress should prioritize legislation that educates patients and providers about the availability and benefits of palliative care and expand federal palliative care research,” Lacasse said. “It’s also crucial all remaining states expand access to Medicaid, as access to comprehensive health care is key to closing the gap on the health inequities we see in these underserved areas and ensure everyone has a fighting chance against cancer.”

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MIKE PETERS, center, performing with The Alarm at Venue Cymru in Llandudno, North Wales on Jan. 28, 2023.

‘This Is MY LIFE’

Welsh musician **MIKE PETERS** wrote ‘Forwards,’ his band’s latest album, while hospitalized with chronic lymphocytic leukemia and pneumonia. By ALEX BIESE

“FORWARDS” IS THE ALBUM

of Mike Peters’ life.

Peters, the singer and guitarist of Welsh rockers The Alarm, gives fans an inside perspective of his cancer journey on the band’s new album. Peters wrote this latest collection of songs, out now via The Twenty First Century Recording Company, while hospitalized for chronic lymphocytic leukemia (CLL). He often used members of his care team as an unofficial sounding board for the new material.

“I think for a lot of them, they didn’t know they were new songs, I was just strumming some chords, playing some things,” Peters said in an interview with *CURE*. “And the girls would say, ‘Yeah, that’s really nice, I’m coming to clean the room again.’”

“Even with the medical staff, I’d be playing. ... I would say to the doctor, ‘Look, I’m a musician, this is my life, I’ve got to get back to being able to play guitar, and that’s why I’m keeping it going.’”

Peters and The Alarm have found a global following over the past 40-plus years. The songs of “Forwards” — with forward-gazing titles such as “Another Way,” “Transition,” “New Standards” and “Next” — were Peters’ personal affirmations at a time when, he said, he was receiving few firm answers from his care team.

“(The medical staff) kept saying, ‘Look, Mike, your life’s going to be very different when we get on top of this,’ and they wouldn’t really say when getting on top of it was or even if getting on top of it was a reality,” Peters said.

“People don’t like to give out hope to patients because it can become false hopes, and they don’t like to give out ideas of outcomes because outcomes might not happen,” he said. “And so, there is a lot of reading between the lines, I think, (that) has to go on for patients now.”

One such instance of reading between the lines led Peters to consult, in his words, “Dr. Google.”

He suspected that he was being tested for Richter transformation, also known as Richter syndrome, an aggressive lymphoma that has been shown to develop in as many as 1 in 10 patients with CLL.

“I could tell it was a real concern,” Peters said. “Without it being voiced until they knew for certain, they wouldn’t tell me about Richter syndrome, and they wouldn’t say it’s not. It was just unspoken, but I knew the testing was going on.”

Peters was negative for Richter syndrome, but that ambiguity, he said, made his treatment situation scary.

“I thought, ‘Well, if it becomes that, then I might not come out of this place,’” Peters said. “And so that plays on your mind quite a lot. And you try to be positive about it all and suppress those darker thoughts. But they come out in the music, they just do.”

“And I think your optimism comes out stronger than your pessimism; for me it does.”

‘My doctors have always warned me about pneumonia’

Peters received a diagnosis of non-Hodgkin lymphoma in 1995, then CLL in 2005; he had a relapse in 2015.

Peters, with The Alarm, has released 23 studio albums, sold more than 5 million albums and charted 17 Top 50



MIKE PETERS of The Alarm wrote the band's new album, "Forwards," while hospitalized due to pneumonia and CLL for two months in 2022.

singles in the United Kingdom. He has balanced cancer care and his music career for decades, touring and recording regularly with The Alarm and as a solo artist.

Jules Peters, Mike's wife and the keyboard player for The Alarm, is a breast cancer survivor who received her diagnosis during the filming of the 2017 BBC documentary "Mike and Jules: While We Still Have Time." A second documentary, "Jules Peters: My Cancer Journey," followed in 2018.

Mike and Jules have continued to support the cancer community with the Love Hope Strength Foundation, which works to expand the bone marrow registry, and by converting a chapel in Wales into a retreat for those affected by cancer.

Mike's leukemia experience continued in the fall of 2022, when he developed a case of post-tour pneumonia.

"As a leukemia survivor with a compromised immune system, my doctors have always warned me about pneumonia," Peters said. "And they'd always told me, if they came to a gig and saw me jumping into the audience or something, 'You shouldn't be doing that.' So when I got pneumonia, I was quite shocked, because it was



SCAN THE QR CODE
to hear Mike Peters discuss his journey on CURE's "Cancer Horizons" podcast.



out of the blue. And I was supposed to rest. The doctors told me I had to stop touring and doing all that, and the only cure for it was to rest."

Peters did what comes naturally to him — he picked up his guitar.

"I thought, 'That's one thing I can do and rest, I don't think you can tire yourself out playing the guitar,'" he said. "And so that got me into the habit of playing guitar on a daily basis, more than I've ever done before, really."

But the pneumonia didn't clear up, and testing revealed his leukemia "was starting to go in a different direction and rear its (head), start to fight back against me. I stopped being able to ingest the drugs that had been working to a point, I started to reject all those," he said.

At Jules' insistence, doctors admitted him to the hospital. What they found was dire.

"My lungs were full of blood," Peters said. "The leukemia was out of control. And my blood count was going up close to 200 (billion) on the white (blood cell) count. And so, they said, 'Look, we're going to have to put you in hospital while we carry out the tests to find what's really going on,' and they had to treat the pneumonia and the lungs first before they could get to the leukemia.

"And then they said to me, 'Right, you're going to be in here for a few months.' ... I had to lie on my side for weeks because I had a drain coming out of my back. At times I was allowed to sit up — when they took me off the IV I was allowed to sit up — and I thought, 'I wish I could have my guitar.'"


Jules brought his guitar and Mike started playing, quietly at first, but soon his work caught on with his fellow patients and staff during his two-month hospital stay.

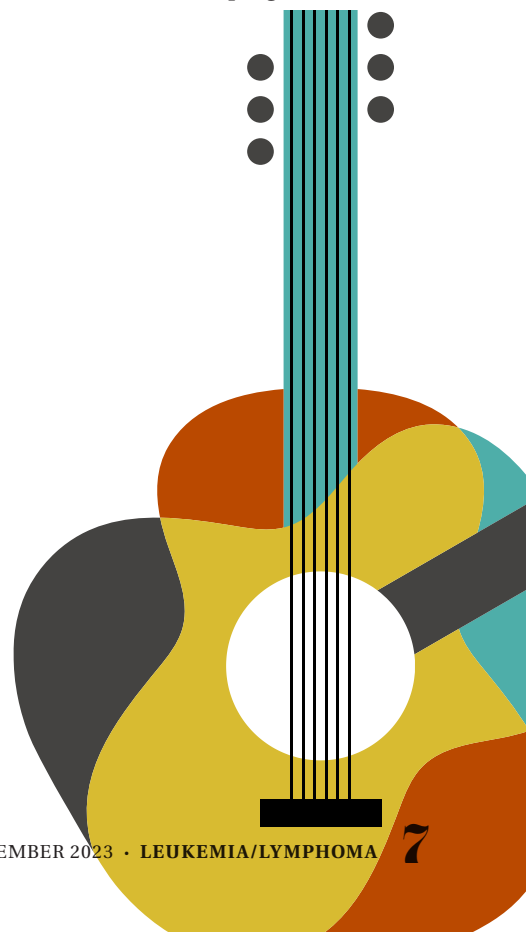
"I wasn't dissuaded from playing the guitar, I was encouraged," he said. "And then, all of a sudden, new songs started to arrive because that's what

happens. And I was in this situation where I wasn't sure what was going on. I wasn't sure what was going to happen next. I wasn't sure if I was going to go to the next world or get to the next chapter in my life."

Peters said he's currently feeling great. He is on a daily dose of Venclexta (venetoclax), takes Rituxan (rituximab) every two weeks and receives monthly immunoglobulin therapy treatments.

"(It's like) I've been in an eternal game of 'Donkey Kong,' because every time I got to the end of a ladder and just running out of the drugs, I get to the next one and there's a new one," Peters said. "Yes, I've been really lucky, whereas a lot of people I've been treated with haven't been so lucky.

"I mean, it's funny, I'm on (Rituxan) now. But seven, eight years ago I rejected (Rituxan); my body wouldn't accept it anymore, and (I) had to go on to different ways of treatment. And now I'm back on it because this (Venclexta) has allowed me to receive (Rituxan). So, you know, I've got the best of treatment keeping me alive." 



NEW HORIZONS

Recent advancements in treatment options for patients with diffuse large B-cell lymphoma have been practice-changing.

By ANDY POLHAMUS

He wasn't expecting a fall during an ice storm to lead to a cancer diagnosis. But that's what happened to Roy Bragadeste, now 55, an engineer at Microsoft.

Bragadeste, who immigrated from Portugal when he was 8 years old and now lives in Washington, went to an urgent care clinic and learned that he had broken three ribs. As a lifelong athlete, he says he "beat (his) body up pretty good" and was used to aches and pains. But this pain in his side and back was different.

"Three months later, the pain never subsided," he says. "If anything, it kind of got worse."

He went back to the clinic, where a doctor recommended that he get a CT scan, though Bragadeste couldn't imagine why. Doctors told Bragadeste he had a mass on his urethra, which was impeding his kidney function and causing his kidney to swell.

He was diagnosed with diffuse large B-cell lymphoma, or DLBCL, in late April 2019. In May, he started chemotherapy. »



ROY BRAGADESTE

received a diagnosis of DLBCL in 2019 and underwent chemotherapy, a bone marrow transplant and CAR-T cell therapy before enrolling in an immunotherapy trial.





NESSA LEE

characteristics made his case particularly high risk.

“I knew it was a very deadly disease,” he says from his home in Jennings, on the outskirts of the city. “I was concerned as to how my family would survive if I wasn’t around. Being a minister, I just prayed and asked God to give me the strength to go through this.”

Morgan, who has been preaching for more than 50 years, recalled the well-known Bible verse in the 23rd Psalm: “Yea, though I walk through the valley of the shadow of death, I will fear no evil, for thou art with me.”

He placed his trust in his faith and in his oncologist, Dr. Mark Fesler at St. Luke’s Hospital in Chesterfield, Missouri, who had recently read and heard lectures about a new treatment option, an antibody-drug conjugate called Polivy (polatuzumab vedotin-piiq).

Morgan and his doctor connected from the moment they met, and Morgan credits Fesler not only with his survival, but with having a real emotional investment in caring for his patients.

Treatment with Polivy and R-CHP (the same as R-CHOP but without vincristine) began in February. By August, treatment was over, and one year later, Morgan was looking forward to his 81st birthday, his body clear of lymphoma.

In April, the Food and Drug Administration (FDA) approved a regimen combining the antibody-drug conjugate Polivy and R-CHP for patients with newly diagnosed, higher-risk DLBCL.

As an antibody-drug conjugate, Polivy works by attaching to proteins on lymphoma cells called antigens.

When Polivy attaches to antigens, it allows the chemotherapy drug bound to the antibody to enter and to attack cancerous B cells more effectively.

“The antibody is a vehicle that carries chemotherapy drugs on it. The antibody allows the poison (chemotherapy) to be targeted

directly to a cancer cell,” says Friedberg, who co-authored the POLARIX study upon which the FDA based its approval of Polivy in this setting. “And at least theoretically, the normal cells aren’t seeing the poison, because the antibody is only recognizing the antigens on the cancer cell.”

In the POLARIX trial, which weighed the effectiveness of the Polivy and R-CHP combination against R-CHOP, Friedberg and colleagues concluded that the Polivy treatment reduced patients’ risk for disease progression or death by 27% compared with the standard of care.



Over the last several months, our practice in the clinic has changed.

— Dr. Manali Kamdar



Furthermore, a slightly larger proportion of patients who were treated with Polivy and R-CHP achieved a benchmark called two-year event-free survival, meaning they did not experience disease progression or complications during that time frame.

Researchers reported that patients assigned to Polivy did not experience side effects at greater rates than those assigned to R-CHOP; people in the Polivy-combination group had a side effect rate of 57.7%, compared with

57.5% in the R-CHOP group.

Similar proportions of people in both treatment groups experienced complete responses, meaning the number of patients whose disease completely disappeared was similar. Also, the overall survival, or total amount of total time that patients lived, was not significantly different.

However, patients taking Polivy spent more time living disease-free.

Friedberg explains this statistic by pointing out that the Polivy regimen lets people live longer without cancer, and that DLBCL is considered a curable cancer.

“So, when you improve progression-free survival in DLBCL at two years, we believe that’s an extremely strong surrogate for cure,” he says.

However, he points out that there are salvageability options for people who relapse. With these additional, more aggressive treatments, Friedberg says, “there’s still a chance at curing the disease.”

Second-line treatment options for relapsed disease (when the disease responds only partially or not at all to first-line therapies) include stem cell transplantation and CAR-T cell therapy.

Two new immunotherapies have been approved this year for use in situations where the transplantation or CAR-T therapy fails.

NEW TREATMENTS FOR RELAPSED OR REFRACTORY DISEASE

Epkinly (epcoritamab-bysp) and Columvi recently became available for patients whose disease has relapsed or not responded to two or more prior treatments.

In May, the FDA approved Epkinly for adults with relapsed or refractory DLBCL. One month later, the FDA approved Columvi for relapsed or refractory DLBCL in the third line and beyond.

Both drugs belong to a type of immunotherapy called bispecific »

FEATURE *diffuse large B-cell lymphoma*

antibodies, meaning they help activate the immune system by bonding to two different targets on the lymphoma cell at once, guiding white blood cells to lymphoma cells and helping them to attack the cancer.

Epkinly works by both bonding to the CD20 antigen, a common marker on lymphoma cells, and engaging CD3 T cells, which are a type of white blood cell that kill the cancerous lymphoma cells.

“The idea behind a bispecific T-cell engager is that it’s an antibody. This antibody has two prongs,” Kamdar says. “One prong sits on the CD20 cell, the B cell. And the other prong sits on the T cell, or the fighter cell, and redirects the fighter cell to kill the lymphoma cell.”

The FDA approved Epkinly, delivered through an intravenous injection, based on results from the EPCORE NHL-1 trial, an open-label, single-arm trial of 148 patients with relapsed or refractory DLBCL.

The main purpose of the study was to evaluate how many people experienced a partial or complete response to Epkinly.

Researchers reported an overall response rate (the percentage of patients with a partial or complete response to treatment) of 61%, while 38% of patients had a complete response. Researchers reported that patients responded to Epkinly for a median of 15.8 months.

“It has shown exceptional responses based on the two pivotal studies that led to FDA approval,” says Kamdar.

The June approval of Columvi, which is also a CD20-directed CD3 T-cell engager, was based on the NP30179 trial.

In that study, which was also an open-label, single-arm trial, 132 patients with lymphoma received the medication. Like the EPCORE NHL-1 trial, the participants in this study previously had at least two failed lines of therapy.

The objective response rate (the portion of patients who had a partial or complete response to treatment) in NP30179 was 56%, researchers reported, whereas 43% of patients experienced complete responses.

Researchers reported that patients responded to the drug for a median

of 18.4 months, and 68.5% responded to Columvi for 9 months.

While Epkinly can be administered for indefinite periods of time, Columvi is currently given to patients for a fixed duration of 8.5 months. And whereas Epkinly is administered by injection, Columvi is delivered by IV drip.

SIDE EFFECTS

All three new treatments come with side effects, many of which are mild, but some of which are serious.

Although side effects occurred at similar rates in both groups of the POLARIX trial, the Polivy treatment commonly comes with fatigue, peripheral neuropathy (nerve damage that occurs away from the spine or brain), constipation, diarrhea, nausea, mouth sores and hair loss.

Its more serious side effects are neutropenia and lymphopenia (low counts of two types of white blood cells).

Nearly 10% of people who took Polivy in the POLARIX trial had to

 **MINISTER EDWARD L. MORGAN**, left, with his son, MICAH, and daughters MORIAH and SHONTREACE.



reduce their dosage because of side effects, compared with 13% of those who received R-CHOP. Similar proportions of people in both groups of the study died from side effects: 2.3% of the Polivy group and 3% of the R-CHOP group.

Morgan experienced some mild gastrointestinal side effects, and neuropathy in his feet and hands as well as fatigue, while taking Polivy.

“I would be kind of weak, and I would just go home and go to bed,” he says.

He opted to receive the chemotherapy portion of his therapy through his arm, rather than through a port in the neck or chest, and developed a necrotic ulcer that required treatment.

Still, Morgan was able to complete treatment without needing to be hospitalized. He continued to preach and teach Sunday school throughout his therapy.

Columvi and Epkinly have side effects similar to those of other immunotherapies.

The most notable of these is cytokine release syndrome, a potentially deadly but manageable condition that can occur when the body’s immune system responds aggressively to infection, or, in this case, cancer cells.

Other common side effects for both drugs include musculoskeletal pain, fatigue and reactions at the injection site.

Epkinly is also associated with fever, abdominal pain, diarrhea and nausea.

The drug comes with a special warning for both cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome, a condition that can cause seizures, aphasia (the inability to speak or process language) and, in severe cases, coma or death.

Experts say, however, that these side effects are usually manageable. It’s also worth remembering that side effects vary from person to person.

Bragadeste says he suffered significantly from CAR-T cell therapy,

his second line of treatment, mostly from losing his hair, which he describes as both physically painful and disheartening. He was also warned about the side effects that might come from Columvi.

“I went (into the Columvi study) fully eyes wide open, knowing that one of the things I might prove is, ‘Oh, there’s this other side effect,’” he recalls.



*I was concerned
as to how my family
would survive if
I wasn’t around.*

—Minister Edward L. Morgan



However, he says he experienced no side effects from taking Columvi.

“It was a very painless, uneventful process,” he says.

Bragadeste also continued to work throughout treatment — not as a show of strength, but as a way of coping. He fully supports people who decide to take time off from work to focus on treatment.

“For me, it was what gave me my only sense of normalcy,” Bragadeste explains. “It wasn’t for Microsoft. It was for me.”

.....
UNANSWERED QUESTIONS **AND**
THE FUTURE OF CARE
.....

Researchers are learning more about DLBCL all the time. Lymphomas comprise a variety of cancers, and Friedberg notes that as research

progresses, the category of DLBCL is being broken down into more subtypes.

Currently, although the Polivy regimen is the new standard for newly diagnosed disease or after relapse following initial therapy, experts do not know which patients with relapsed or refractory disease are better suited to Epkinly or Columvi.

Dr. Yasmin H. Karimi, a co-author of the EPCORE NHL-1 trial that led to the approval of Epkinly, says that while a variety of factors can play into a patient’s initial prognosis, there is not enough data available right now to tell whether Epkinly or Columvi is preferable based on a single person’s disease characteristics.

“We do not know yet how to select therapies based on risk factors at the time of progression,” she explains. “That’s why we talk about other factors, like side effect profile, patient preferences and administration.


“The biggest limitation is not being able to predict who’s going to respond to which treatment.”

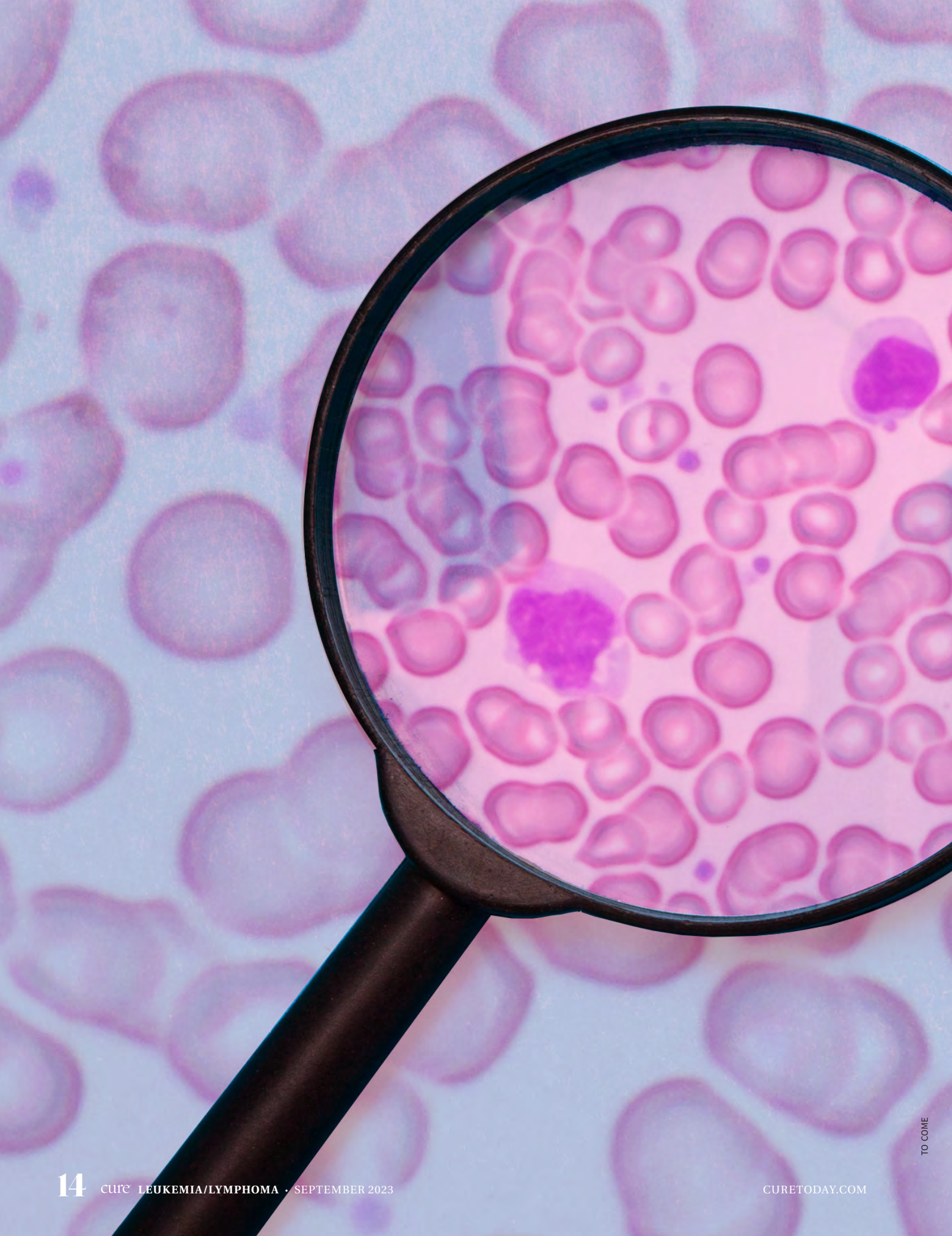
Karimi and her colleagues are still monitoring people who took part in the EPCORE NHL-1 trial.

In addition, future research of both Epkinly and Columvi will likely focus on new ways to use the drugs.

“On the horizon, it’s about getting these excellent agents either with better combinations, or to test them in an earlier-line setting,” Kamdar says. “For example, we do have a study with a CD20 (bispecific antibody) and (Polivy). And impressively, they have had great responses.”

He expressed great optimism for the future.

“I do believe that things are looking really good for patients with DLBCL,” says Kamdar. “But clearly, we need to continue to strive to do even better.” 



ON THE LOOKOUT

Why minimal residual disease testing is the 'gold standard' for some patients and providers

By ALEX BIESE

When Michael Ray went to his doctor for an annual checkup two years ago, he felt fine. But the bloodwork results of the Boston-area native now living in Naples, Florida, told a different tale.

“My white blood cell count was a little high,” says Ray, now 48. “And just through testing, my doctor eventually said, ‘I think we should test you for leukemia.’ I was shocked. I had no idea. I didn’t even really know what leukemia was at the time.”

A bone marrow biopsy later confirmed that Ray had chronic myeloid leukemia (CML).

“The first three months were difficult, very difficult,” Ray says. “I mean, you just have a lot of questions: ‘Why me?’ ‘How did this happen?’ ‘How could this be true?’

“I think (it’s) pretty much what most people probably go through when they get a cancer diagnosis.” »



«
For **MICHAEL RAY**,
a “little high” white blood cell
count on standard bloodwork
led to a diagnosis of CML.

have the abnormality that’s going to cause cancer? And that’s when we start to look (at) the genetics of those cells for minimal residual disease. Or, instead of relying on a pathologist’s eyes to look at a bone marrow sample, we’re putting the blood through a machine called flow cytometry and we’re allowing the machine to detect very small amounts of those cells that are still left over, that may not be apparent to a pathologist looking at a bone marrow sample or a blood sample.”

CML has long been a target of MRD due to its specific genetic abnormality, commonly referred to as the Philadelphia chromosome, two chromosome pieces fused together forming the BCR-ABL mutation, which drives the development of CML.

“When the drugs that we now use as standard procedure were introduced into CML and the first of those drugs, Gleevec (imatinib), was approved in 2001, soon after people realized that a decrease in the amount of BCR-ABL that was detected was associated with people who had better responses to the drug and were less likely to have their disease get worse,” Sekeres said. “So, we’ve been using BCR-ABL as a minimal residual disease (indicator) now for 20 years.”

Ray, who describes Gleevec as “a miracle drug,” says his time between BCR-ABL tests is still stressful.

“About a week out before the testing, I start to get really nervous, (I have a) hard time sleeping, I just start to get really scared that the

“And then, after the first three months, when you have your first big test — the BCR-ABL test (which quantifies the amount of residual leukemia remaining) — and you see that the medication’s working, you start to feel better,” Ray says. “You start to realize that it’s not a death sentence.”

Ray is a patient of Sylvester Comprehensive Cancer Center, part of UHealth, University of Miami Health System, where the chief of the division of hematology, Dr. Mikkael A. Sekeres, explains that the BCR-ABL test that gave Ray some peace of mind has been established for decades as the standard means of determining minimal residual disease status in patients with CML.

Minimal residual disease, also referred to as measurable residual disease or MRD, is an assessment of malignant cells remaining in the patient’s body following treatment. “When we do a bone marrow biopsy on somebody for leukemia, we give that bone marrow sample to a pathologist who then looks at it under a microscope ... and leukemia cells can be apparent to the eye or they can become more apparent when a pathologist adds markers, dyes, to the bone marrow,” Sekeres explained. “So, they’re looking in a field in a microscope for abnormal cells.

“But what if you can look for cells that may look on the outside as normal, but inside they actually

other shoe is going to drop, let's say. You're going along good, you feel good and everything, but you don't know if the numbers are going to be good or not," Ray says.

INCREASED CHANCE OF CURE?

Although MRD assessments have been more developed for some types of cancers than others over the past couple of decades, experts are optimistic regarding further advancements.

"These are really the future for guiding the very best therapies," says Dr. Michael Pulsipher, division chief of pediatric hematology at Intermountain Primary Children's Hospital and Oncology, director of the Children's and Adolescent Cancer Initiative at Huntsman Cancer Institute and a presidential chair in pediatric oncology and hematology at the University of Utah. "Over and over again, we've seen examples of how MRD is the best predictor for outcome and (how) it can help us know when to increase or decrease therapies.

"So, in the future, I see this, as our testing gets more sophisticated, (as) being really the best way to ... tailor what needs to be given to a given patient. So, in the future, more and more diseases will be having these type of minimal residual disease responses or cell-free DNA assessments to see whether we're treating (patients) the way we should."

By studying blood or bone marrow cells via tests such as flow cytometry and next-generation sequencing, MRD assessments for types of leukemia and lymphoma can "detect one leukemia cell among 10,000 to 1 million normal cells," according to Dr. William Wierda, section chief for chronic lymphocytic leukemia in the department of leukemia, division of

cancer medicine at The University of Texas MD Anderson Cancer Center in Houston.

Wierda, also the coauthor of the 2021 chronic lymphocytic leukemia recommendations published in *Nature*, explained via email that MRD "is a way to assess or measure the depth of remission achieved with treatment. If the number of leukemia cells is below the limit of detection, patients are said to have achieved undetectable MRD status. Undetectable MRD status is correlated with longer remission and survival following treatment."



*You feel good ...
but you don't
know if the
numbers are
going to be
good.*

— Michael Ray



MRD results can be of great help to patients whether they are positive or negative, Pulsipher explains.

"It won't necessarily ease (the patient's) mind, but it will increase their chance of cure," Pulsipher says.

Patients with acute lymphoblastic leukemia (ALL), Pulsipher says, who display an "exceptional response" to treatment and are MRD negative after a month of treatment, "have such a good prognosis that it's

predicted that 98% of the time, they will be cured. ... It doesn't mean you don't have to take your two years of therapy, because you do. What it does mean is that your chance of cure is exceptionally high."

Patients who are MRD-positive, on the other hand, are categorized as high risk.

"Is your outcome terribly worse? No, but your treatment is more intense," Pulsipher says. "But the patient shouldn't feel terrible about that. They should feel relieved that, 'Oh, good, they know that I have to have this extra therapy, but my chance of survival with the extra therapy is still really good.'"

A "worst-case scenario," according to Pulsipher, is when a patient considered MRD positive and high risk is still showing a high MRD value following a second month of treatment.

"There's just no getting around it; that's going to be bad news to a patient. They're going to feel like they failed. But in reality, they haven't failed," Pulsipher says. "They ... may never have gotten into good remission and may never have gotten curative therapy, but now that we know that they are (in) the 5% that are very high risk, and we get them to either transplant or CAR-T (cell therapy) or both early, that improves their chance of cure.

"So, if someone can have Zen and can say, 'It's OK if I get news from my MRD that I need more intensive therapy because it's maximizing my chance of cure,' then you'll be OK."

'GIVE MRD TIME'

Dr. Andy Rawstron, clinical scientist at the Hematological Malignancy Diagnostic Service in Leeds, England, stated in June at the European Hematology Association (EHA) 2023 Congress that MRD is "one of the strongest predictors of what's likely to happen in the next »

few years” for patients with chronic lymphocytic leukemia, but it is not without its predictive limitations.

“You’ve got to give MRD time,” Rawstron said. “It’s not an early predictor of outcome unless you look just at the very high levels. You’re using MRD to say what’s going to happen five, 10 years ahead.”

cancer) was 64% for patients who were MRD negative — more than double that of the 25% rate for MRD-positive patients. Likewise, the estimated overall survival rate (the time that a patient is still alive following treatment) was 68% for MRD-negative patients and 34% for those who were MRD positive.

According to Wierda, there is no

“The current data for MRD (support) doing the test at the end of fixed-duration treatment, which would be (Venclexta [venetoclax])-based or chemoimmunotherapy-based treatment, to assess the depth of remission,” Wierda says. “There (are) no data to use this information to support extending the treatment to achieve undetectable MRD status. So, (the data are) not used to make any treatment decisions, only to understand depth of remission.”



(MRD tests) are really the future for guiding the very best therapies.

— Dr. Michael Pulsipher



**‘THERE ISN’T
STANDARDIZATION’**

Wierda says that there are several ongoing trials evaluating the use of MRD in treatment, related to topics such as duration of treatment and changes to treatment if undetectable MRD status is not achieved. MRD, Wierda says, “is also an important test when evaluating new treatments for curative potential, since undetectable MRD status must be achieved if we are aiming at developing curative treatments.”

However, some debate remains in the field — particularly, according to Sekeres, regarding the best way of assessing MRD, and standardization of that assessment.

“One lab assessing minimal residual disease may disagree with another lab that’s looking for the same abnormality,” Sekeres says. “And that’s the trick with it — that there isn’t standardization across labs of how they measure minimal residual disease and how they define that.”

A team of researchers in a study in the journal *Frontiers in Oncology* said MRD assessment has been “transformational in the landscape of CLL clinical trial design and reporting. With an increasing number of MRD-directed end points, the next challenge is how MRD assessment will be integrated into routine clinical practice, which will also require

Appearing at EHA, Rawstron’s final slide made his position clear: “Is MRD assessment necessary? Not in routine clinical practice yet, but MRD is likely to play a central role in developing the treatment of the future.”

**ASSOCIATION WITH
REMISSION AND SURVIVAL**

An investigation into the association of MRD with survival outcomes among patients with acute myeloid leukemia (AML) published in *JAMA Oncology* found that, in a review of 81 publications studying more than 11,000 patients, the estimated five-year disease-free survival rate (the time following treatment that a patient lives without signs of

debate regarding the association between undetectable MRD status following treatment and longer remission and survival.

“There is no trial that has shown that treatment should be continued until undetectable MRD status is achieved, so community providers do not use it for this purpose but can use MRD assessment at end of treatment to understand the depth of remission for a patient and if a long remission duration can be expected based on this test result,” Wierda says.

The *Nature* paper co-written by a team including Wierda and Rawstron stated that, at the time, there was “no clear role for MRD assessment” in routine practice. In the past two years, that has changed — to a point.



SUE D'AGOSTINO

has her bloodwork checked every three months and trusts her MRD test results. "I have to put faith in that," she says.

evaluation from both patient benefit and health economic perspectives."

However, the researchers also noted that it "remains to be demonstrated that deeper MRD necessarily predicts a better clinical outcome in all clinical situations. At present, MRD has been linked to disease prognosis and used to tailor treatment duration, but it remains to be demonstrated whether MRD-driven therapeutic decisions will always be clinically beneficial or sufficient to challenge the traditional CLL treatment paradigms."

'I HAVE TO PUT
FAITH IN THAT.'

Sue D'Agostino, a two-time breast cancer survivor, was caught off guard when, in 2020, the discovery of enlarged lymph nodes during her annual mammogram led to her receiving a diagnosis of CLL.

"Of course, I first turned to Dr. Google, who told me I was dying," D'Agostino, a 63-year-old native of Akron, Ohio, says. "And so, I don't recommend that for anybody."

D'Agostino then joined a Facebook support group for patients with CLL where, she says, she "got a little bit more confidence that it's not curable, but it's manageable. So, I thought, 'I can do this.'"

Following the advice of the Facebook group, she connected with a CLL specialist who discovered via biopsy that D'Agostino had CLL in 90% of her bone marrow and then referred her to a clinical trial.

During the trial, D'Agostino received three rounds of infusions of the chemotherapy bendamustine and the monoclonal antibody Rituxan (rituximab), after which her CLL had plummeted to 2% of her bone marrow in just three months. She then moved on to the next phase of the trial: targeted treatment with

Venclexta (venetoclax), along with six additional treatments of Rituxan, with a blood sample sent to the Mayo Clinic for MRD testing.

"My first one came back and (it) was April of (2021), and they said I was MRD negative," D'Agostino says. "So, they test one in 10,000 and 100,000 cells and I was in complete remission in my blood." A September 2021 biopsy found that she was also in remission in her bone marrow.

D'Agostino still has her bloodwork checked every three months and trusts her MRD results.

"I have to put faith in that, because that's all I have," she says. "And I haven't seen anywhere that anybody has said that the MRD is not like the gold standard to tell you where your cell count is. "So, at this point, because that is to me the gold standard, I don't doubt it. I firmly believe in it. I mean, we don't have anything else." ■

SPEAKING OUT TREATMENTS AND TRIALS



‘Patients Should Be **EMPOWERED** to Ask’



On behalf of the Leukemia and Lymphoma Society, an expert discusses seeking the best treatment and exploring clinical trials.

By ALEX BIESE

THERE IS A “WONDERFUL” problem” for people working in the leukemia and lymphoma space, according to Nikki Yuill, oncology social worker and director of the Leukemia & Lymphoma Society’s (LLS) Information Resource Center: an increasing number of treatment options for patients with blood cancers. Yuill, in a recent conversation as part of *CURE*’s “Speaking Out” video series, discussed how patients can seek the best possible treatments and explore the process of enrolling in a clinical trial.

Q: **When discussing patients with leukemia and lymphoma, who are the candidates for treatment?**

A: Ideally, we want all (patients with blood cancers) to have access to the best treatments for their disease. Even in our subset of (patients with blood cancers) who (receive a diagnosis of), let’s say, an indolent lymphoma, or possibly CLL (chronic lymphocytic leukemia), where they are in what’s called “watch and wait” or active surveillance where they don’t actually need to start treatment right away, it’s

still really important for these patients to be even considered for potential participation in a clinical trial, and that they’re being monitored closely.

We want all (patients with blood cancers) to be able to explore clinical trials as a treatment option at any point in their diagnosis, including those who (have just received diagnoses), and, of course, especially those who may be relapsed and refractory. Now, there is always going to be a small subset of patients (who) may have an illness that is refractory and they’re needing to transition into palliative care or palliative care along with hospice care, end-of-life care. Those are (members of a) difficult subset of patients. But again, we want to make sure, no matter where people are in their journey, that they have access to the support and care that they need.

Q: **Given the array of treatment options available, and the fact that more are becoming available every year, how can patients and their care team decide on the best course of care?**

A: This is getting more and more complicated as we have this wonderful problem, I guess, of having lots of treatment options that we didn’t have even, let’s say, five years ago for many of our (patients with blood cancers). But one thing that we always want to keep in mind throughout any part of their journey is clinical trials. Clinical trials are the primary vehicle for developing new treatments for patients (with) cancer. And for many patients, this could provide the best treatment option possible for their cancer, yet we know that only a small fraction ultimately enrolls in a clinical trial. So, this part is important.

And, of course, there (are) also vastly underrepresented groups within that clinical trial subset ... and when looking at clinical trials, one of

the things we want to do is overcome barriers. How do we get more people to participate? How do we get people access to even know what their treatment options are?

The second piece is those conversations with their health care team and helping patients and families, and this is important for caregivers as well. What questions should we be asking to know what all our treatment options are before we make that informed decision? So (it's about) talking, and again, we go back to communicating with your doctor and your health care team and knowing what questions to ask to make sure that all options are considered.

At LLS, (for) our (patients with blood cancers who) are interested in a clinical trial, we will refer them over to our clinical trial nurse navigators in our free Clinical Trial Support Center. This is one-on-one, individualized care and support through the entire clinical trial search process and even beyond enrollment if there's still support needed after that.

Regarding clinical trials, what conversations should patients be having with their doctors to identify whether there is a trial out there that is right for them?

Q:

A:

What you just said is that initial question to your provider.

Even if your provider has not brought it up themselves, you should empower yourself and patients should be empowered to ask, 'What clinical trials might I be a candidate for? And how do I initiate that search? I really want to know; I want to make sure that all my options are out on the table and then we can have that discussion about the pros and cons and maybe why I wouldn't be eligible for certain trials.'

But it's (about) asking that question and empowering patients and families to even inquire about clinical trials to make sure that it's not missed. That is the start. ... (And it's) important for people to know that there's help there and they don't have to do all that research

themselves. (It's) much better to have an expert, such as a clinical trial nurse navigator, help with that process.

Q:

A:

Are there efforts or initiatives underway to increase and expand clinical trial enrollment?

This is one big part of our mission here at LLS — not just increasing the numbers of patients (who) are enrolled in clinical trials, but also paying special attention to diversity in clinical trials and representation. And we have a couple of different programs that I would like to mention: One of them is our impact (research) grants that are also part of the diversity in clinical trials. Our Office of Public Policy is also involved at a state and federal level on efforts to increase diversity in clinical trial enrollment. And then we also have research grants that are specific to increasing enrollment in rural areas in clinical trials, so again, this is an area that's near and dear to LLS. 

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