

Immunotherapy a hot topic in treating cancers

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Last Friday was Rebecca Hertzog Burns' birthday. She turned 2. She says that's her age, though she's really 27. After a relapse in her fight with acute myelogenous leukemia, Burns received a stem cell transplant on Sept. 9, 2014, through an infusion of umbilical cord blood from a baby boy.

By her way of thinking, she and her immune system were reborn that day. "My new birthday," says Burns, who has been in remission since.

The treatment she received at the University of Kansas Hospital falls within a broad spectrum of care called immunotherapy. It is the hot topic, the "it" word, in addressing <u>cancer</u>. While doctors report success combating several types of cancer through different versions of immunotherapy, KU clinicians say some of the most remarkable stories arise in the treatment of blood cancers.

Deadly forms of leukemia and lymphoma, which commonly strike young adults such as Burns, are now managed, and in many cases vanquished, using treatments unavailable just a few years ago.

"In 26 years of practice, this is absolutely the most optimistic I've ever been," said Joseph McGuirk, medical director of KU's blood and marrow transplant program. Patients from around the world travel here to take part in experimental trials.

"It's not hyperbole at all to say we're in the middle of a revolution in



cancer therapy," he added.

The idea behind immunotherapy is to coax a patient's own body to attack cancer cells. The way of doing that - in short, by harnessing the immune system to do the work that cancers don't let it do - differs from patient to patient, from cancer to cancer.

For former President Jimmy Carter, suffering from an advanced melanoma that many thought would kill him, the key may have been a "checkpoint inhibitor" drug with the brand name Keytruda.

Carter last year stunned the globe when he announced that his immunotherapy treatment, combined with radiation and surgery, eradicated tumors that had developed in his brain and liver.

Immunotherapy isn't new, but it's getting a lot of attention now for a reason, said McGuirk, a soft-spoken physician reluctant to trumpet medical breakthroughs before they've been proven to work.

"We've reached this critical mass where, kaboom, all of sudden (immunotherapy) has taken off like a rocket," he said.

National news media are jumping aboard, largely because of Carter's success. The U.S. government and drug companies pour billions of dollars into research, and clinical trials underway at KU and hundreds of other facilities have produced strong data.

By itself or in combination with other treatments, immunotherapy is being credited for putting some terminal <u>cancer patients</u> - but far from all - in remissions that can last for years.

Some of the drugs being developed block a mechanism, the immune checkpoint, that cancer exploits to keep the immune system at bay.



Other treatments remove from patients millions of disease-fighting cells, reconfigure them in a lab and infuse them back into their sick owners.

The hope is for these so-called T-cells to do the job they're meant to do.

KU clinicians credit immunotherapy as one of the treatment paths that has allowed more blood-cancer patients to enjoy extensive remissions than ever seen before. The final blow to their disease is often an allogeneic stem cell transplant, which can rebuild the immune system from scratch.

Still, many patients don't respond to these treatments.

For them, conventional steps such as chemotherapy and radiation remain potential lifesavers. But in those treatments' quest to attack all cells they can get, and not only cancer cells, their side effects usually are much harsher than immunotherapy's.

Others warn that too much hype around immunotherapy could steal attention and funding from those more traditional strategies and other promising treatments.

"Through the history of oncology, there are periods in which something gets really hot and everyone gets excited that it's the answer," said Otis Brawley, chief medical officer for the American Cancer Society.

"The immunotherapy treatments being developed are here to stay. But I worry about research and money shifting away from other approaches."

The Kansas City Star chose to look at immunotherapy - and tell a story of hope - through the lives that converge on the third floor of the Richard and Annette Bloch Cancer Care Pavilion in Westwood.



It's where McGuirk works with blood-cancer outpatients. Many of them, running out of options, have joined clinical trials that made them immunotherapy test cases.

None of the patients in this story is out of the woods. But at least their bodies are fighting.

In the spring, a dying Artesha Singleton of Kansas City traveled to a St. Louis hospital to see if she might qualify for an experimental trial.

No, you're too sick, a physician told the leukemia patient. Return to Kansas City and find a hospice program. You've got a few months.

She's only 27. That she relies on Missouri Medicaid for coverage doesn't help.

"I think the way they treated her was pretty monstrous," said Haylie Colby, a social worker at KU's Westwood clinic.

Singleton was diagnosed at Truman Medical Center just last summer. She has a 2-year-old son. When she returned from St. Louis, she spent three days crying in her bedroom.

All of the approved therapies for Singleton were exhausted. Rounds of chemotherapy had no effect. "What do we do next?" asked Shaun De-Jarnette, the quality management coordinator at KU's blood and marrow transplant unit, or BMT.

The team overseeing Singleton's case knew that the drug manufacturer Pfizer was testing a product not yet on the market: inotuzumab ozogamicin. Though not an immunotherapy drug, it might reverse



Singleton's deathly slide enough for her later to benefit from a stem cell transplant.

"We were desperate and asked Pfizer to give it to us," said physician Leyla Shune. "For free."

Under a provision that the U.S. Food and Drug Administration calls "compassionate use," Pfizer agreed.

Inotuzumab ozogamicin saved her. And with her cancer in remission, Singleton became a candidate for a transplant that would turn her immune system into that of a newborn baby's. (As of Sept. 9, her immune system was just a week old.)

Resting in her hospital bed before the procedure, which took less than an hour, Singleton said, "I feel wonderful."

Her aunt Regina Roberson was at her side. "It's been a bumpy, bumpy ride," Roberson said. "But the treatment we found here is working. She's living proof."

In June, the *New England Journal of Medicine* reported encouraging findings on Pfizer's investigative drug. The treatment led to "complete remission" in 80 percent of trial patients with relapsed acute lymphoblastic leukemia.

Chemotherapy alone produced that result in only about 30 percent of patients.

KU's McGuirk said similar success is being found in an immunotherapy drug called Blincyto, which put patient Emily Fox's leukemia in remission.



Fox, who has worked with cancer patients as a nurse, was diagnosed in February with cancer of her own. At the BMT unit, "from the first day they were telling me, 'We're going to get rid of that cancer,' " said Fox, 28. "I believed them."

But McGuirk cautions against overconfidence. False hope helps nobody dealing with cancer, whether it's a patient or members of the clinical team who still see too many lives lost.

"Immunotherapy is hit or miss," McGuirk said. "We've got a long, long way to go."

And it's expensive. Patients whose insurance requires that they pay 20 to 25 percent out of pocket could spend \$25,000 or more for a year of treatment on drugs such as Opdivo, approved for both melanoma and lung cancer.

Leonard Saltz of the Memorial Sloan Kettering Cancer Center in New York last year told a meeting of oncologists: "As someone who worries about making cancer care available to everyone and minimizing disparities, I have a major problem with this. These drugs cost too much."

"There are so many kinds of immunotherapy," said Mitch Schwarz, 24, of Blue Springs. "I've done two."

The first didn't work. Relapsing in 2014 in his bout with blood cancer, Schwarz for a month wore a backpack that contained <u>immunotherapy</u> medicine. The solution traveled through a tube to his chest.

But the treatment wasn't achieving the desired result. Schwarz's immune



system wasn't recognizing the cancer cells as a threat to be devoured. When the treatments succeed, it's "like Pac-Man," said McGuirk.

KU doctors ultimately directed Schwarz to a clinical trial in Seattle, where he underwent a brand of treatment called CAR T-cell therapy. "It was either this or certain death for me," he said.

Unlike chemotherapy and radiation, which kill cells both good and bad, Schwarz's treatment in Seattle was customized to get his body to target just the bad cells.

His blood was drawn and disease-fighting T-cells were taken to a lab for "gene editing." The re-engineered cells were returned to his body and, if the therapy worked, they would attach to malignant cells and start punching.

The treatment has put Schwarz's cancer in remission and, like the others, he became ready for a <u>stem cell transplant</u>.

"I'm 115 days out of that transplant, so my <u>immune system</u> is that many days old," he said last week at the Westwood clinic. He visits weekly to have blood work done.

The results so far look encouraging, his doctors said.

"It's exciting," Schwarz said. "My cells are working. I hope they fight like hell."

A former Kansas City area resident now living in Fayetteville, Ark., Burns returned to the KU Cancer Center in late August for her two-year checkup.



Everything looked good.

For lunch that day, Burns spoke to a group of three dozen hospital directors and benefactors about the leukemia that developed when she was 20.

She thought she had it licked once but relapsed in 2014, right after boyfriend Tanner Burns told her father about plans to marry her.

She told her boyfriend he couldn't propose until she was well. Her voice trembled recalling that story. "It really broke my heart," she said.

Introducing Rebecca Burns to the group, McGuirk called her story "absolutely miraculous."

Slides of her recovery after her transplant showed her clowning with the BMT staff. "Some of these nurses are my closest friends," she said.

She continues to post her progress in a journal on the website Caring-Bridge.org, where sick persons can keep their loved ones updated.

In a recent entry she noted: "Pray for my overall health and wellness ...
This battle is far from over!"

She's only 2, after all.

As for her and Tanner, they married in July.

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