

TMC!PULSE



NEWS OF THE TEXAS MEDICAL CENTER — VOL. 6 / NO. 4 — MAY 2019

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WILLIAM F. McKEON

*President and Chief Executive Officer
Texas Medical Center*

It's hard to go even a single day without hearing about the promise of artificial intelligence (AI), which is increasingly deployed in a broad spectrum of products and services. To many, the term stimulates excitement and curiosity, while others worry about AI's impact on humanity.

We are quickly realizing the benefits that AI can provide to humans. In cars, for example, cameras, sensors and software can identify objects quickly approaching the vehicle and apply the brakes faster and more efficiently than a human could—all while avoiding distraction. Retailers have implemented AI to predict with astonishing accuracy what we will buy before we actually place an order to ensure speedy delivery. Almost every commercial flight is landed by AI software that simultaneously interprets thousands of sensors in real time and makes the necessary adjustments.

In medicine, artificial intelligence is making a difference in many ways. For example, when machines review MRI images to identify abnormalities like tumors, they can draw on a library of millions of other images to reach a conclusion. Often, machines can perform this task more quickly and with more accuracy than a human ever could. But that's just the start.

At the Texas Medical Center, we conduct more research on our campus than any other place on Earth. The challenge we face—and that clinical researchers around the world face, too—is the arduous process of finding and matching patients for clinical trials. This process requires researchers to manually sift through patient records. As a result, it typically takes months to find just a few patients for each trial.

Here at the TMC, we are beginning to implement an AI platform that will transform this sorting process from months and years to minutes and seconds. This could provide life-saving opportunities for our patients. It could help draw more industry to Texas. And eventually, it will establish the Texas Medical Center as not only the largest medical city in the world—but also the most efficient.

A handwritten signature in black ink that reads "William F. McKeon". The signature is fluid and cursive, with a long horizontal stroke at the end.

TMC | PULSE

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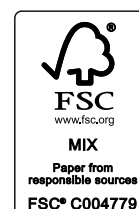


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ON THE COVER: TMC³ will link the Texas Medical Center's clinical and research campuses and serve as an icon for Texas.

(Rendering by Elkus Manfredi Architects)

Textured breast implants linked to cancer

The U.S. Food and Drug Administration (FDA) recently held a two-day hearing on the long-term safety of a specific type of breast implant that is linked to a rare cancer that grows in the scar tissue around the breast, known as breast implant associated-anaplastic large cell lymphoma (BIA-ALCL).

The FDA reported 457 confirmed cases of BIA-ALCL in the United States, all linked to textured breast implants. For women in the U.S. with textured implants, the current lifetime risk of BIA-ALCL runs between 1 in 3,817 and 1 in 30,000.

"It's devastating," said Alan Matarasso, M.D., president of the American Society of Plastic Surgeons (ASPS). "But we have to recognize that this is a device, and as much as we study it and as much as we try to perfect it, it adds a third factor into the equation of surgery. It goes beyond just the patient and the surgeon; it [includes] the device. ... We have to look at this and study this to get our arms around it."

The rough surface of textured implants allows them to adhere to surrounding tissue, which makes them less likely to become repositioned in the implant pocket. Smooth implants, on the other hand, settle faster in the body and tend to create a more natural look.

The FDA and the ASPS maintain that breast implants are safe devices. Although France recently decided to ban textured implants, most of the 19 panelists at the FDA hearing and many experts in the medical community say a similar measure in the U.S. would be premature.

Symptoms can look like other illnesses

Common symptoms of BIA-ALCL include pain, a swelling or hardening of the breast due to fluid collecting around the implant and a discrete mass or lump in the breast or armpit.

These symptoms are similar to other, more common, conditions and are more likely indicative of other issues or illnesses, said Sebastian Winocour, M.D.,

assistant professor in the Michael E. DeBakey Department of Surgery at Baylor College of Medicine and member of the Dan L Duncan Comprehensive Cancer Center at Baylor.

"Infections or sterile seromas ... are far more frequent than ALCL," he said.

A woman with symptoms should talk to her physician, who can perform a physical exam and order tests—including magnetic resonance imaging and ultrasounds—to check for any suspicious lumps or swelling. In the presence of fluid or a mass, a physician will then perform a needle biopsy to test for BIA-ALCL.

No testing or screening is available to women who are asymptomatic. If caught early, BIA-ALCL is completely curable by removing the implant and the surrounding scar tissue.

BIA-ALCL causes are still unclear

The direct cause of BIA-ALCL is still unknown, but doctors and scientists are focusing on implant texture, bacterial contamination and geographical location.

Patients with smooth implants who develop capsules of scar tissue around the implants sometimes opt to replace them with textured implants, which have been shown to reduce the risk of scar formation. BIA-ALCL has been found most frequently in patients undergoing implant revision operations for persistent seroma—a fluid-filled pocket that often develops after surgery, according to the FDA.

In addition, some studies have shown that bacteria in the breast lymphoma triggers a long-term inflammatory response, Winocour said.

Researchers have also identified a possible geographical and genetic variability in BIA-ALCL cases. For example, Australia and New Zealand reported a higher incidence of BIA-ALCL than the U.S., with a 1 in 1,000 to 1 in 10,000 risk with textured implants.

"All three of those factors are at this point associations. They're not causations," Winocour emphasized. ■



Textured breast implants offer a different feel and mobility compared to smooth implants.

BREAST IMPLANTS AND BIA-ALCL

550,000 total breast implants

are placed per year in the U.S., including

70,000 textured breast implants

457 confirmed cases of BIA-ALCL in the U.S.

9 known deaths* in the U.S., may be attributable to BIA-ALCL

Source: American Society of Plastic Surgeons
*As of 4/12/19 based on FDA report.

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Undocumented Mexican Immigrants Plagued by Loss and Distress

A new study examines the psychology of this at-risk population

BY ALEXANDRA BECKER

Approximately 18 years ago, a little boy and his mother entered the United States illegally. The young boy suffered from congenital heart disease and needed a new heart. His mother, fleeing severe domestic abuse, hoped they could build a new life in America and that she could get her small son the specialized medical care he so desperately needed.

Years passed, but the undocumented boy was never considered for the transplant list. His condition progressively worsened until he was finally placed in palliative care. Today, he relies on morphine to control the pain that pulses throughout his body. His mother remains by his side, but she, too, is dying—waiting for a liver transplant that will never come.

This story was collected in clinical interviews that took place between Nov. 2014 and Jan. 2015. In all, 248 undocumented Mexican immigrants residing near the California-Mexico border were interviewed by researchers who wanted to examine the prevalence of migration-related loss and its association with ongoing trauma and psychological distress. Results of the study appeared in a paper titled “A High Price Paid: Loss and Distress Among Undocumented Mexican Immigrants,” published by the *Journal of Latinx Psychology*.

Luz Garcini, Ph.D., a postdoctoral research fellow in Rice University’s department of psychological sciences and the study’s lead author, stressed the importance of these interviews in collecting her data.

“If we were to do the clinical interview using traditional measures and with a traditional diagnosis—without really knowing the context of how this young adult was living—he would come out as a drug addict,” said Garcini, who also serves as a faculty scholar at the Baker Institute for Public Policy at Rice and will soon join the The University of Texas Health Science Center in San Antonio as an assistant professor at The Center for Research to Advance Community Health. “The stress and the high level of depression and anxiety and the constant amounts of medically related drugs that he was consuming—he would have come out of the study as someone with substance abuse, which is the stereotype that is so prevalent in this community. That’s why it is so important to get the story, to find out who these people really are.”



Credit: Photo by Michael Nigro (Sipa via AP Images)

A visitor to the Tijuana side of the U.S.-Mexico border places his hand on a painted heart.

Loss and trauma

Garcini, who worked alongside colleagues at Rice as well as researchers at the University of Denver, the University of New Mexico, the University of Central Florida and The University of Texas at Austin, discovered that the rate at which undocumented Mexican immigrants suffer psychological and physical losses related to their migration was much higher than previously understood.

“We knew there was a high prevalence of loss and trauma in this population—we expect it because we know the many challenges they face. However, they were so much higher than I could even imagine, particularly in terms of repeated exposure or multiple losses,” Garcini said.

The study’s participants were mostly female, married and living on a household income of less than \$2,000 a month. The majority had been in the U.S. for more than 10 years.

Researchers divided the different types of losses into separate categories, including the

symbolic self, interdependence, home, interpersonal relationships and interpersonal integrity. They found that migration-related loss was high across all categories. Even more, these losses were linked to clinically significant psychological stress—especially loss of interdependence related to being treated differently by others for not having a visa.

Yet despite what seemed to be endless suffering, the people who shared their stories were remarkably strong, Garcini said.

“One of the most striking things is that, regardless of the amount of loss and trauma, they are very resilient,” she said. “I would say, ‘It seems like you’ve endured a lot in your life and you have lost a lot. How are you doing? How would you describe your life here?’ And they would say, ‘It’s very good.’ And I would say, ‘But you’re struggling. You’re facing loss and trauma,’ and they would say, ‘Yes, but you don’t know where I come from. This is much better than what I left behind.’” ➡

Individuals who seemed most resilient, she said, often had three things in common: a focus on family, a job and strong spirituality.

Living in fear

The Pew Research Center estimates that 10.7 million undocumented immigrants resided in the U.S. in 2016, half of whom originated from Mexico. Approximately one-quarter of the U.S. foreign-born population is unauthorized immigrants.

Garcini hopes that the results of this study will help her and others identify new strategies to reduce the negative effects and mental health

concerns among this at-risk population and start implementing intervention, policy and advocacy efforts. She is now involved in studies that take this data a step forward by using blood tests to assess how stress and trauma affect physical health and physiological function.

“The purpose is to also identify some of the protecting factors that could lessen that impact on their health,” Garcini explained. “Once we identify that, we’ll be able to develop and build interventions that could be disseminated to the community through collaboration with social agencies or faith-based communities.”

Some of the most important collaborators,

Garcini said, are clinicians.

“We hope these results will raise awareness among providers to develop best practices with these populations,” Garcini said. “It’s always important when you see these families that you have in the back of your mind that there’s a very high possibility that they might have experienced trauma, or they might not disclose certain health conditions because of fear.”

That fear has been compounded in recent years amid a political and social climate that has grown increasingly hostile toward undocumented immigrants.

“The rhetoric has escalated against immigrants, particularly undocumented and particularly people of Mexican origin,” Garcini said. “We have seen increased discrimination, threats—you can imagine that the loss and the trauma is going to be much, much higher.”

Interviewees who had been eager to speak with Garcini in 2014 were afraid to speak with her when she returned this past December.

“People didn’t want to talk,” Garcini said, “and these people know me.”

Beyond mental health

A constant state of anxiety keeps many undocumented immigrants from receiving sufficient care for mental and physical health issues. Further complicating the situation is the fact that this population is almost always uninsured.

“Generally, these patients are able to get some care at these federally qualified health centers that see patients regardless of citizenship and regardless of insurance, but these centers don’t have all the specialists that are required,” said Rajeev Raghavan, M.D., an associate professor of nephrology at Baylor College of Medicine who sees many undocumented patients in renal failure who are in need of dialysis or a transplant. “Oftentimes these patients really go untreated and the disease becomes quite severe.”

Raghavan believes that policy change on a federal level is critical.

“We knew there was a high prevalence of loss and trauma in this population—we expect it because we know the many challenges they face. However, they were so much higher than I could even imagine, particularly in terms of repeated exposure or multiple losses.”

— LUZ GARCINI, PH.D.



Luz Garcini, Ph.D., is a postdoctoral research fellow in Rice University's department of psychological sciences and a faculty scholar at the Baker Institute for Public Policy.

“This patchwork of solutions where one state does one thing and one state does another is not fair to the patients and it makes it much more complicated for the health care system to provide care when it’s fragmented,” Raghavan said. “This is really a national problem ... so having some uniform policy makes sense.”

For now, though, federal policy seems to be moving in the opposite direction. On Oct. 10, 2018, the Trump administration proposed a change to what is known as the “public charge” rule. According to U.S. Citizenship and Immigration Services: “Any individual who is likely at any time to become a public charge is inadmissible to the United States and ineligible to become a legal permanent resident. However, receiving public benefits does not automatically make an individual a public charge.”

Trump’s proposed change adds more programs to be considered when determining if a person is likely to become a public charge, including health care organizations previously considered “off-limits” because of the essential services they provide, such as Medicaid, Medicare Part D, housing assistance and the Supplemental Nutrition Assistance Program (SNAP). Although these changes have yet to be implemented, misinformation and rumors have sent ripples of fear throughout immigrant communities.

“People are really afraid. It’s created a lot of

misconceptions and misunderstanding,” said attorney Wafa Abdin, executive director of Houston Volunteer Lawyers, which provides pro bono legal aid. Abdin said she’s even seen immigrants who are excluded from the public charge rule avoid accessing services because of it.

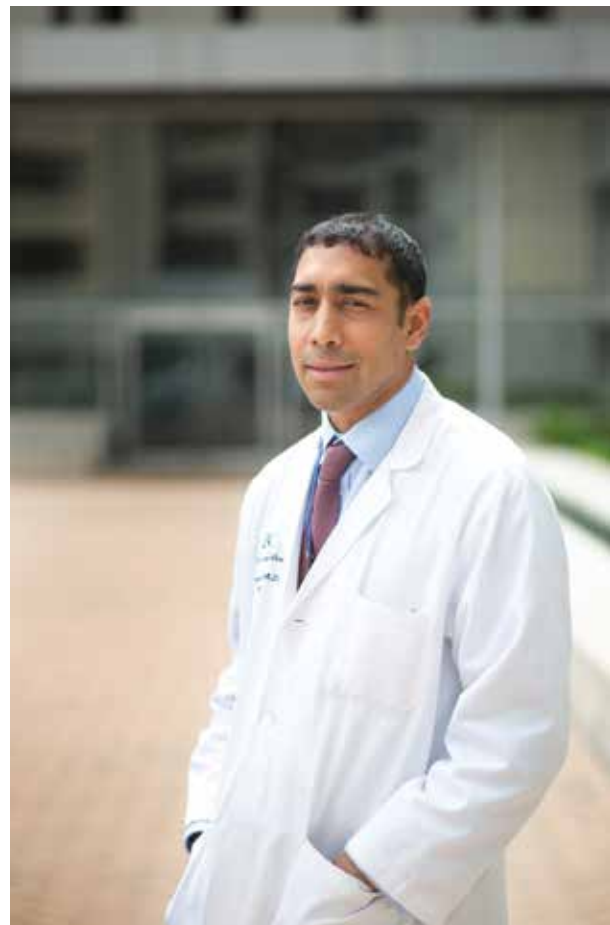
“There are families that don’t really know how much it will affect them, so they are starting to stop asking for these benefits,” Abdin said.

Living in fear is the status quo for many undocumented immigrants.

“They’re not sure when they drop their kids at school whether they’ll be able to pick up the kids because every undocumented immigrant has become a priority with the change of priorities as a result of the executive orders,” Abdin said. “There is this atmosphere of fear added to those who even have hope of getting some kind of status. They really don’t want to even touch anything that might jeopardize them.”

For those who work most closely with this population, the current patchwork of solutions and the threat of even more stringent guidelines for aid is devastating, Garcini said.

“When you study the context and you learn the story, you realize that the majority of these people are struggling, that they come here with a purpose, that they want to work, they want to better their lives,” she said. ■



Rajeev Raghavan, M.D., is an associate professor of nephrology at Baylor College of Medicine.

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JIM McINGVALE is best known in Houston as “Mattress Mack,” owner and operator of the Gallery Furniture retail chain and star of his own homespun television commercials. But the Mississippi native is also an active philanthropist who has donated millions to numerous charities, community programs and medical initiatives in Houston. McIngvale spoke with *TMC Pulse* about helping finance the BiVACOR total artificial heart, supporting mental health and opening his store to Houstonians during Hurricane Harvey.



Q | You and your family moved from Starkville, Mississippi, where you were born, to Dallas, Texas, when you were three years old. Then you relocated to Houston in 1981 to open Gallery Furniture. What brought you to Houston?

A | My wife [Linda] and I came down here with \$5,000 and the hope that we could make something happen. And, by golly, we're still here all these years later.



We were working together at this fitness center, and then we were dating. I told her I was going to move down to start this furniture store and I asked her to come with me and help me do it. She said, 'I'll only do that if you marry me.' We got married and here we are. It's been happily ever after for 38 years.

Q | In 1990, a doctor walked into Gallery Furniture to ask for your help. That doctor was Billy Cohn, M.D., chief emergency resident at Ben Taub Hospital at the time, now vice president for Johnson & Johnson Medical Devices Companies and the executive director of the Center for Device Innovation at the Texas Medical Center. Tell me about your initial encounter with him.

A | I was up here working and this surgeon walks in in his surgical scrubs. He's got blood all over him. It was Billy.

He hadn't shaved in three or four days. He says, 'Hey, we've got the new Ben Taub Hospital and the county's run out of money, so all of the people that are waiting in the emergency room while their loved ones are being operated on are having to sit on the floor. Can you get us some recliners?' I said, 'How many do you need?' He said, 'We need a whole truckload, 40 or 50 or something.' I said, 'Sure, I'll get them for you.' I got him all those recliners and we shipped them down there to Ben Taub, but they wouldn't take them. They didn't have hospital foam in them, so they weren't flame retardant. That's why I remember the story. They sent them back to us. He called very apologetic. We called and ordered them with hospital foam and got them back down there to him.

Q | You encountered Cohn again in 2008 when your brother, George, was suffering from congestive heart failure.

A | My brother was very sick, and I was down there at St. Luke's to have a meeting with Dr. [Bud] Frazier about how they were going to save my brother's life. Billy walked in with Bud.

I would be down there visiting my brother at 12, 1, 2 o'clock in the morning after I got off work, and I'd be kneeling by his bedside. Even though he was in a coma, he knew I was there because we were very close. And Bud would come in there and check his charts and nurture him.

Bud would talk to me, and I would say, 'Dr. Frazier, it's 2 o'clock in the morning. What time do you operate tomorrow?' And he said, 'I operate at six.' I said, 'Do you ever sleep?' He said,

'Yeah, I go up there in my office and sleep three or four hours. I'll be fine.'

I [asked] one night, 'Why do you do all this?' He said, 'My patients are my life.' You got to love a guy like that.

Q | Frazier and Cohn wanted to work with Daniel Timms, Ph.D., creator of BiVACOR, a next-generation total artificial heart designed to replace the function of a patient's failing heart. You decided to invest \$2.1 million to bring Timms from Australia to Houston. What motivated you to get involved with BiVACOR and the team?

A | At the end of the day, it's all about patients. If we can do something through BiVACOR that helps people live longer, healthier lives and get back their quality of life, then I've done something good for the world. I'm not going to be here forever, so my wife and I both want to try to leave a legacy.

What we need is somebody to invent a battery that can power this artificial heart through the skin without having to have wires coming out, because those wires cause infection and they limit a person's lifestyle. If any aspiring entrepreneur at the Texas Medical Center wants to invent a battery that can power that heart through the skin, let me know. That would be a great movement forward in the BiVACOR artificial heart business.

According to Billy and Bud, in the next year or two, they can get it implanted in a human and we'll see what happens. Lots of history at the Texas Medical Center and, thanks to Daniel Timms, Dr. Frazier and Dr. Cohn, hopefully they'll make some more.

Q | Your daughter, Elizabeth McIngvale, Ph.D., serves as an assistant professor of psychiatry and behavioral sciences at Baylor College of Medicine and is an active mental health advocate who was diagnosed with severe obsessive compulsive disorder (OCD) when she was 13 years old. At the time, some doctors said her condition was too severe to be treated. How did you respond to that?

A | My wife and I are eternal optimists. One way or another, we weren't buying the prognosis that our child would never amount to anything, that she would never graduate high school, that it was best to put her in a mental institution for the rest of her life. We weren't buying that and we were going to find a way. ➡



I talked to the people I knew at the Texas Medical Center. Linda searched the internet and we finally found a lady who recommended The Menninger Clinic, then in Topeka, Kansas. We took Liz up there and she went to six or eight weeks of intensive therapy, then came back to Houston and had another relapse. By that time, Menninger had moved to Houston.

It's been a long journey, but we learned a lot and, knock on wood, she's doing well, although she continues to battle the mental illness every day.

Q | What were some of the most difficult experiences you remember as she was struggling with her condition?

A | Her being suicidal was extremely tough on the whole family—especially on her—and for her to be unable to control those rituals and compulsions that she knew made no sense and were illogical, but she had to do them anyway because of mental illness. All that was extremely tough.

But you know, we're people of faith and you've got to keep the faith. You've got to just keep believing. We all want to be life forces for good, and my life force says that the good Lord never sends any of us anything we can't handle.

Q | How do you determine which issues and organizations to support?

A | I think the majority of people, when it comes to philanthropy, probably give to things that have affected them personally. My beloved brother and my father both died of congestive heart failure, so that's why I'm involved in BiVACOR. I've had some mini strokes and this and that, that's why I'm involved with the Mobile Stroke Unit, which is a partnership between UTHealth and Memorial Hermann-Texas Medical Center. At the same

“Houston gives everybody an opportunity to do well. All Houston ever said to me was, ‘Kid, here’s a chance for you. A chance to succeed, a chance to fail. It’s totally up to you how hard you want to work to succeed.’”

time, we give a lot to education and things that we deem are good for the city, good for the state.

Q | You opened Gallery Furniture to victims of Hurricane Harvey. What was going through your mind when you decided to offer up your business as a massive crashpad?

A | I was up at the front desk and the phone was ringing off the wall and the emails were exploding and the text messages were ding, ding, ding—nonstop, people saying, ‘Come rescue us! We’re going to drown!’

We’d done a pretty good job of preparing for the hurricane by having all these big trucks here get through a lot of water, but what we hadn’t prepared for was the fact that none of our employees could get to work because they were all flooded in, too. I did a Facebook Live and put out a notice we needed people with commercial drivers’ licenses to come drive these trucks and rescue people. They came in and we sent them out. We had to get in the game real quick. There wasn’t a lot of planning. That’s the way I was brought up: Do the right thing and worry about the cost of whatever later. And that’s what we did.

We were all energized, the ones of us that were

here doing it, by the courage of the people that we brought in. They waded through four to six to eight feet of dirty water to get here and they were devastated, but they had a good, positive attitude. You saw the strength of the human spirit.

Q | What is your most poignant memory from that time?

A | I think the first night we had 200, 300 people sleeping in here, so we had the air conditioning cranked down real cold. They were sleeping in furniture blankets, the only blankets we had. But they were sleeping on these couches, on the mattresses, they were sleeping everywhere. It was still raining very heavy outside—very hot, very humid, but it was cold in here.

About 2 o’clock in the morning, the door opened and this little girl came in with her people—I believe her parents and her uncle. They were all four just sopping wet because they had waded through three or four feet of dirty water on the feeder road. She was the only one out of the four who spoke any English. She saw me up there, but she was afraid to come up to me. Finally, I motioned for her. She’s wet and hot and traumatized and dirty and scared to death. Now she’s freezing because she’s in this cold furniture store and her little teeth are chattering.

She comes up to me and says, ‘Can we stay here tonight?’ That was it.

It was a no-brainer. That’s the way I was brought up. You worry about people, not about money. Money, you can make some more tomorrow, but people, you only get one shot.

Q | It’s clear that you care very deeply about Houston. What do you love most about the city?

A | I think the fact that nobody in Houston asks you where you’re from or what your educational level is. Houston gives everybody an opportunity to do well. All Houston ever said to me was, ‘Kid, here’s a chance for you. A chance to succeed, a chance to fail. It’s totally up to you how hard you want to work to succeed.’ And I think that’s the story of Houston. We’re multicultural, multiethnic and anybody can succeed in Houston if they want to roll up their sleeves and go to work. ■

Jim McIngvale was interviewed by Pulse staff writer Shanley Pierce. The conversation was edited for clarity and length.

NEXT MED

New technology and techniques

By Ryan Holeywell

Welling up with real tears

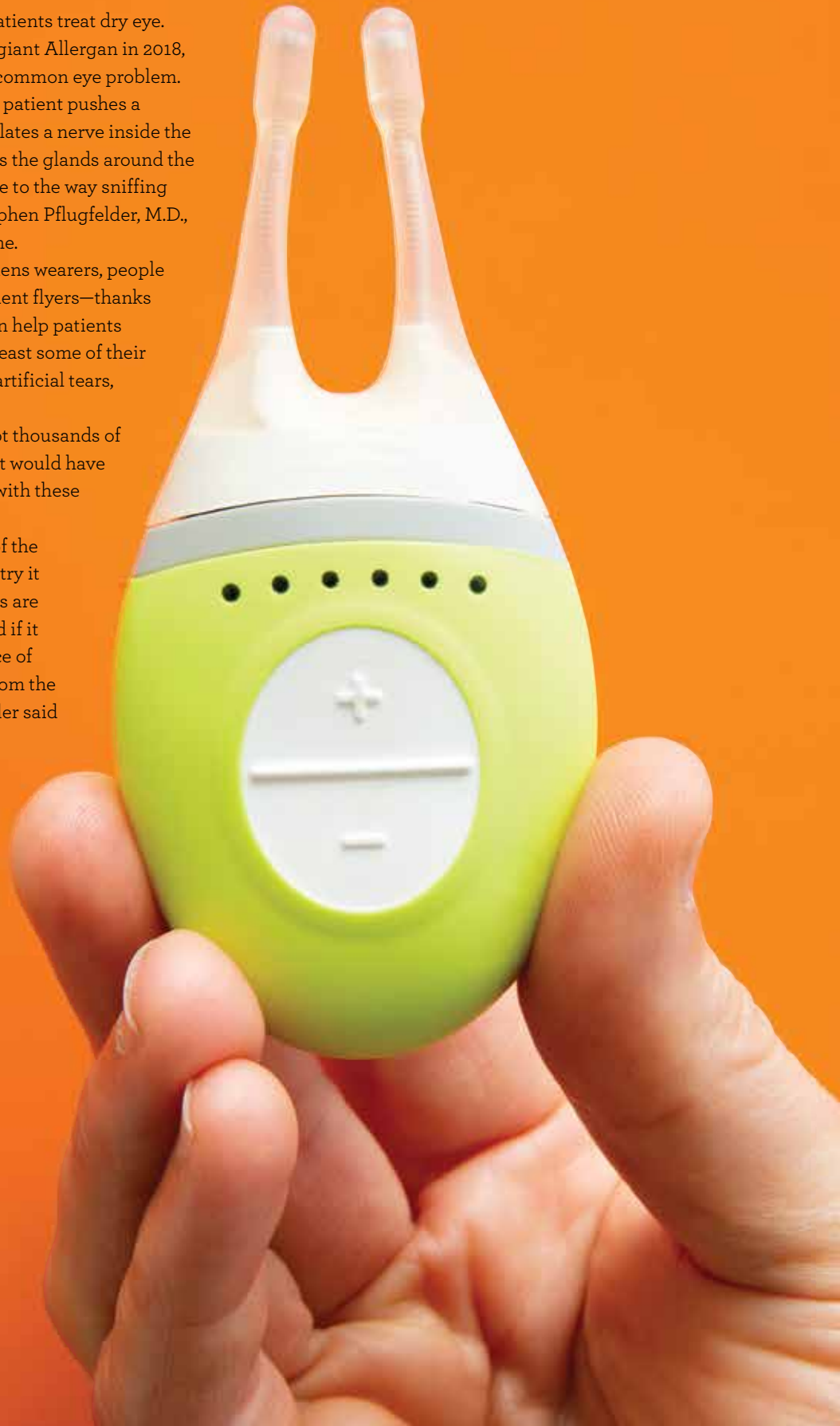
A new device offers a shocking way to help patients treat dry eye. TrueTear, launched by pharmaceutical giant Allergan in 2018, provides a drug-free, drop-free treatment to the common eye problem. After inserting the device into the nasal cavity, a patient pushes a button to release a pulse of electricity that stimulates a nerve inside the nose. That signal is sent to the brain, which alerts the glands around the eyes to generate tears. This trigger is comparable to the way sniffing onions can cause a cook's eyes to water, said Stephen Pflugfelder, M.D., an ophthalmologist at Baylor College of Medicine.

Dry eyes are a common problem for contact lens wearers, people who work in front of computers all day and frequent flyers—thanks to low humidity levels on airplanes. TrueTear can help patients who still have the physical ability to produce at least some of their own tears, which are far better for the eyes than artificial tears, Pflugfelder said.

"It turns out that tear fluid has hundreds if not thousands of factors—mucus, antibodies, things like that—so it would have more of a healing potential for the eye to coat it with these natural molecules," he said.

Some of Pflugfelder's patients are skeptical of the device initially, but they warm up to it once they try it a few times. He estimates about 30 of his patients are using TrueTear and he believes even more would if it was more affordable. Allergan described the price of TrueTear as "variable," since physicians buy it from the company and set the price for patients. Pflugfelder said the device costs more than \$1,000 and generally isn't covered by insurance.

This spring, Pflugfelder will begin a clinical trial to determine if TrueTear can also aid with production of mucus cells in the eye, which help maintain the stability of tears. ■



A NEW GOLD STAND

Houston news personality Frank Billingsley is part of a clinical trial to treat prostate cancer with gold nanoparticles

Gold has built fortunes and inspired Olympic dreams, but can it treat cancer?

A team of doctors and researchers aims to find out, with help from patients including local meteorologist Frank Billingsley.

“Gold is a safe material and it has been used in humans for hundreds of years,” said Steven Canfield, M.D., chief of urology at McGovern Medical School at The University of Texas Health Science Center at Houston. “Think about all of the people who have gold fillings in their teeth for their whole life.”

Canfield has partnered with researchers at Rice University, medical device company Nanospectra Biosciences and the Icahn School of Medicine at Mount Sinai in New York City to perform a small clinical trial using gold nanoparticles to treat prostate cancer.

The gold nanoparticles, known commercially as AuroShells, were developed by biomedical engineering professor Naomi Halas, Ph.D., principal investigator for the Halas Research Group at Rice University and Nanospectra. Made of silica glass and wrapped in a thin layer of

gold, the AuroShells are about 50 times smaller than a red blood cell and act as tumor-seeking missiles when they enter the patient’s bloodstream. They are the main component in the AuroLase therapy used on patients in Canfield’s clinical trial.

“The particles naturally find the cancer,” Canfield said. “They diffuse throughout the whole body and they deposit in areas that are highly permeable. Anywhere that you have a lot of inflammation, the nanoparticles would deposit there.”

The two Franks

Billingsley, chief meteorologist for NBC-affiliated television station KPRC2 in Houston, was the third patient enrolled in the clinical trial in Houston. He announced his cancer diagnosis on the air and the rest, as they say, is history.

“Dr. Naomi Halas, who invented the gold nanoparticles, saw my story on Channel 2 and said, ‘Get in touch with Frank. He might be a candidate!’ So they did and I was,” Billingsley recalled. “Regardless of



Left: Steven Canfield, M.D., chief of urology at McGovern Medical School at UTHealth, pours liquid containing gold nanoparticles into a beaker. Canfield is leading a clinical trial to treat prostate cancer with the nanoparticles, known commercially as AuroShells, which are made of silica glass and wrapped in a thin layer of gold.

Right: Frank Billingsley announced his prostate cancer diagnosis on NBC-affiliated KPRC2 in Houston, where he is chief meteorologist.

ARD

BY BRITNI R. McASHAN

whether I was on TV or not, if I had never said anything and they hadn't heard my story, they wouldn't have known to get in touch with me."

For Halas, it was a different Frank who inspired her work to find a less invasive way to treat prostate cancer.

"We found Frank Billingsley as he was in the process of exploring other treatment options," Halas said. "When I met him, I said, 'Frank, you have the same first name as my dad,' so it came full circle. My father, Frank Halas, a prostate cancer survivor, was diagnosed in 2007. He had radiation therapy at age 85 and it is really, really damaging. That is why we are so incredibly excited about this treatment. My dad said to me, 'If you can prevent just one man from going through what I had to go through, it will be worth it.'"

Before Halas and Canfield contacted him, Billingsley was considering other options to treat his prostate cancer, but they were grim.

"Although prostate cancer is the second-most deadly cancer for men these days, the problem is not really so much mortality as it is morbidity," Halas said. "People who go through the traditional treatment have just a devastating loss of quality of life."

Traditional treatment plans include a radical prostatectomy—the removal of the entire prostate gland—as well as radiation and hormone therapy. ➡



“The problem with radical treatment for prostate cancer is removing the whole prostate or radiating the whole prostate along with testosterone suppression therapy has a lot of side effects,” Canfield said. “It can lead to urinary problems including incontinence, sexual problems and impotency—sometimes permanently. Radiation can lead to scarring and bladder and bowel problems, and hormone treatments can make people incredibly tired and have all sorts of other medical complications.”

In stark contrast, the patients in Canfield’s clinical trial are treated with AuroLase therapy. In this two-part process, patients are infused intravenously with a black solution containing the gold nanoparticles (AuroShells) on the first day and sent home to allow the nanoparticles to disperse throughout the body and find the cancerous tumors. The next day, the patients return for laser therapy.

“This is an outpatient procedure. You don’t have to stay in the hospital; you could theoretically be feeling great the next day,” Canfield said. “That is quite different from surgery. Even with minimally invasive surgery now, there is still going to be a recovery period. With radiation, you are looking at at least eight weeks of treatment, and the smallest time frame of hormone suppression you are going to get is six months. For high-risk disease, you are looking at two years or more, so it is an incredibly different quality-of-life treatment.”

When the patient comes back for the second phase of the AuroLase treatment, laser light is applied to the lesions where the nanoparticles have collected most heavily. Using MRI imaging and an ultrasound device, doctors seek and destroy cancerous areas. To target these areas, a trocar (normally used for laparoscopic procedures) is placed into the lesion and a catheter is inserted in the prostate gland, precisely where treatment is desired. Once the targeted location is identified, doctors remove the cancerous areas with a laser by heating up the nanoparticles to make the gold vibrate and destroy the disease.

“This is an outpatient procedure. You don’t have to stay in the hospital; you could theoretically be feeling great the next day.”

— STEVEN CANFIELD, M.D.

Chief of urology at McGovern Medical School at UTHealth

The nanoparticles are designed to absorb light in the area of the electromagnetic spectrum called the “near infrared,” the region closest in wavelength to radiation that is perceptible to the human eye.

“The nanoparticles, when you shine light on them, will absorb light very efficiently,” Halas said. “Then they convert the light to heat and they’ll heat in their local vicinity so they have an extremely localized heat source—so they heat only where the particle is placed.”

\$6.50 worth of gold

Billingsley hardly missed a beat after his treatment.

“I had it done on Wednesday, I was at a Christmas party on Saturday and back at work on Monday. It was a quick, easy recovery,” he said.

The worst-case scenario is that the gold nanoparticles undertreat the prostate cancer so there might be a sliver missed—most likely because the lasers didn’t activate those areas, Canfield explained.

That would be a miss and a treatment failure. But you don’t miss the chance to do any of the traditional treatments you had been considering in the first place, he added, and because prostate cancer is so slow growing, nothing is really likely to have changed and you probably removed the vast majority of the cancer even in a failure case.

“At the end of the day, they only put about \$6.50 worth of gold in me,” Billingsley said. “It was exciting to be on the forefront of anything in Houston—we are that kind of town. We have the best med center in the country, if not the world. Our space program, our sports programs ... I’ve watched them all grow up in 20 years. Television is always on the cutting edge of technology, so the business I’m in is always out there doing something pioneering. To take a chance on something that I thought made sense in a community that I trusted didn’t bother me.”

The clinical trial is being conducted at UTHealth, Mt. Sinai and the University of Michigan.

“Now, all three sites have patients enrolled,” Canfield said. “This first phase of the trial has 45 clinical patients and we are up to 39 patients so we need six more and this trial will end. We have already started to plan for the second trial and that will be, in total, 55 patients. That will be enough for the FDA to start approving us as an available treatment.”

Canfield and Halas hope the AuroLase therapy will be expanded to treat other cancers in the near future.

“I think skin cancer would be an ideal candidate for this treatment. There are lots of ways you can saturate a skin cancer,” Canfield said. “You can saturate it with nanoparticles and you can just activate those by shining a light just over the skin. You don’t have to put it inside the body or anything. Kidney, liver, breast cancer—anything where you can see the area and then place a laser there will work well.” ■



Jon Schwartz, Ph.D., director of clinical research at Nanospectra Biosciences, holds a laser with an illuminated guide light, used in the clinical trial.



CURATED

The Intersection of ARTS and MEDICINE

By Britni R. McAshan



Artist and naturalist Christopher Marley arranges insects, birds, crustaceans, fish, plants and reptiles in precise, 3-D displays that make viewers feel as if they've stepped into a bejeweled natural kaleidoscope.

Biophilia: A Dialogue with Art, Nature and Science, Marley's new exhibit at the Houston Museum of Natural Science (HMNS), immerses visitors in the beauty and diversity of the natural world.

"Biophilia is a term that literally means a love of life or living things and that, in one word, encompasses how I feel about the natural world," Marley said in a statement within the exhibit. "As a naturalist, my education has been almost entirely experience-based in the fields and the forests. I was watching these entire little ecosystems functioning and interacting with one another and it was a pivotal moment for me to connect with the natural world."

The geometric arrangements of animal, mineral and plant specimens force viewers to consider nature in a new context.

"If you look at these organisms on their own in their natural environment, you might think they are scary or dangerous," said Erin Mills, entomologist and director of the Cockrell Butterfly Center at HMNS. "But this exhibit presents those creatures as artwork and allows viewers to see them in a different way."

Walking through the exhibit, one cannot help but notice the immaculate condition of the hundreds of thousands of specimens. Marley collected them in an environmentally sensitive way, by either reclaiming them, as he did with vertebrates and blooms, or culling them sustainably, as he did with oceanic invertebrates and insects.

"I employ natives in these different ecosystems to sustainably harvest common species," Marley said in a statement. "It gives the locals a way to make a living and it also reverses the economic pressure to develop that habitat."

As humans, it is also important to remember that we rely on these species for survival. From jewel-toned insects to rainbow-colored parrots and carnivorous plants, all the specimens play a vital role in the planet's ecosystem and, in turn, human health and survival.

"It's kind of like Jenga," Mills said, referring to the classic block-stacking game. "What happens if you take out the one piece that is holding everything together? These species do so much to pollinate and even eat plants. They have such an intricate relationship in all of our food webs that it all builds on itself. These species are also great indicators of the health of an environment, so if you remove even one of these creatures, it could be devastating." ■

Biophilia: A Dialogue with Art, Nature and Science will be on display through September 2 at the Houston Museum of Natural Science, 5555 Hermann Park Dr. Information: 713-639-4629.

A LEAP FORWARD FOR TMC³

Updated design includes “DNA necklace” that spans the length of the campus

BY RYAN HOLEYWELL

The Texas Medical Center’s TMC³ campus is undergoing critical updates to its design, including the introduction of green space that extends even further across the campus and provides a crucial link within the medical city.

The TMC³ translational research campus, slated to open in 2022, will serve as a nexus between TMC’s clinical and research campuses. Importantly, it will foster “collisions” between doctors, researchers, entrepreneurs and others, facilitating the essential links needed to grow and sustain the area’s innovation ecosystem.

“We didn’t want to create an isolated district—we’re creating a hub,”

said architect David Manfredi, CEO of Boston-based Elkus Manfredi, the firm designing TMC³. “It’s the glue that makes the connections between all these places and creates opportunities for unintended collisions. It’s all about the interaction of institutions, industry and startups.”

Elkus Manfredi Architects, Transwestern

and Vaughn Construction will serve as the architectural and development team that will design and build the campus.

The project was announced in April 2018 at a press conference led by Texas Gov. Greg Abbott, Houston Mayor Sylvester Turner and the leadership of the five founding TMC³ member institutions: the Texas Medical Center, Baylor College of Medicine, Texas A&M University Health Science Center, The University of Texas Health Science Center

at Houston (UTHealth) and The University of Texas MD Anderson Cancer Center.

The 37-acre campus will be located east of Bertner Avenue and west of Cambridge Street, extending from Braeswood Boulevard on the north side to just south of Old Spanish Trail.

“The Texas Medical Center is eager to move forward with a bold, imaginative and dynamic new design vision for the TMC³ Master Plan,” said TMC President and CEO William “Bill” McKeon. “With the combined talents of Elkus Manfredi, Transwestern and Vaughn Construction on board, I couldn’t be more confident that this dream team will flawlessly execute the totality of the project’s vision and fulfill its mission to bring together leading researchers and top-tier expertise from the private sector to create the No. 1 biotechnology and bioscience innovation center in the world.”

Notably, the updated plans call for an elongated green space promenade—known as the “DNA necklace”—that spans the entirety of the TMC³ campus. A series of lens-shaped green spaces will be interlaced with a walkable and drivable street grid, allowing for easy access.

“The most memorable things on many college and university campuses aren’t the buildings but the spaces,” Manfredi said. “We wanted to make great, open spaces that will attract people not just from the Texas Medical Center, but from the entire city of Houston.”

The project will include individual lab buildings and mixed-use space on the ground floor. Situated along the green space will be collaborative facilities, retail and residential opportunities and a hotel and conference center. Parking will be housed underground to optimize the street-level space for walkability, amenities and communal interactions.

The goal is to create a true “live, work, play” ecosystem.

“You can attract talent with great research and facilities, but if you



David Manfredi is the CEO of Elkus Manfredi Architects, the firm designing TMC³.



Above: A series of connected green spaces will span the length of the TMC³ campus. The perimeter will be lined with restaurants and retail, while the green spaces will feature frequent events and programming. **Below:** The TMC³ Collaborative—the main, shared building at the center of the campus—will offer research space in its upper floors and an open atrium at the ground level that is designed to host lectures and other events. Credit: Renderings by Elkus Manfredi Architects

don't have great places to live and a great social environment, people move on," Manfredi said.

Elkus Manfredi is a leader in the design of medical innovation space, with a portfolio that includes the Innovation and Design Building in Boston's Seaport district, the Stanley Building at the Broad Institute in Cambridge, Massachusetts, and the New York Genome Center.

The main, shared building at the center of the TMC³ campus will be known as the TMC³ Collaborative. Its upper floors will house shared institutional research space and industry partner facilities. The downstairs atrium, where lectures and other events will be held, will serve as a natural gathering space, where personnel engaged in different types of works for different organizations will interact.

"We're creating a place where all of the stakeholders come together for different reasons," Manfredi said. "We want the researchers, we want the industry people and we want the students. This is the place to make those connections."

The "DNA necklace" will include a series of green spaces, each spanning about three-quarters of an acre. Manfredi said the design accomplishes two important goals. The DNA strand will be an instantly recognizable, iconic image associated with the Texas Medical Center. More practically, the distinct green spaces could be programmed differently. One might be a serene park, another might feature music and

performances and still another might host sports like volleyball or basketball.

"People will feel like they want to be there because they're constantly stimulated—whether it's breakfast at the coffee place, or a volleyball league in the afternoon or working in a central lab space where the person next to them is doing something interesting," Manfredi said. "At the end of the day, we're in the business of attracting and retaining talent." ■



How Long Do Transplanted Organs Last?

It all depends on the organ and the recipient

BY BRITNI R. McASHAN

On July 7, 1990, Randy Creech got a second chance at life when he received a new heart. But the transplant came with an expiration date.

"I was sitting at home and I got a call from St. Luke's Hospital," Creech said. "They said, 'A 19-year-old man has died in Amarillo, Texas, and we have a heart for you.' All of the waiting had come to an end. The first thing that came to my mind was that I was about to head down a path that I couldn't reverse."

Months earlier, the otherwise healthy 40-year-old learned during a routine physical that he had an irregular heartbeat caused by a viral infection. Creech's heart was failing and he was placed on a waiting list to receive a new heart on, of all days, Valentine's Day.

"They told me if everything goes well, you'll probably get about five years out of it," Creech said, referring to his donated heart. "Five years sounded really good when they had just told me I had less than a year to live without a new heart."

That was nearly 29 years ago. Creech is still living with the same donated heart.

At the time of Creech's surgery, transplant surgeons were reinvigorated with hope for successful transplants because breakthrough anti-rejection

drugs had been released into the market.

"In 1970, Dr. DeBakey stopped doing heart transplants because he believed the problem of rejection was so severe that it wasn't the right time to do them," said Ahmed Osama Gaber, M.D., director of Houston Methodist J.C. Walter Jr. Transplant Center.

After 12 unsuccessful transplant surgeries in two years, Michael E. DeBakey, M.D., halted transplant surgeries at Houston Methodist and turned his attention to the artificial heart. Fourteen years later, DeBakey resumed the program when he believed the cost and effort of organ transplantation was worthwhile for patient success.

In a 1984 *New York Times* article, DeBakey said: "With the advent of cyclosporine, the results of transplantation, heart transplantation, lung transplantation, as well as kidneys, have all improved significantly, and we should expect a

five-year survival rate of better than 50 percent, dealing with patients at the terminal stage of heart disease."

Cyclosporine, the first drug successfully used to prevent organ rejection, works by weakening a patient's immune system to help the body accept a new organ. After cyclosporine was approved by the U.S. Food and Drug Administration in 1983, Gaber said, survival rates after transplant surgeries jumped from 55 to 60 percent after one year to 80 to 85 percent after one year.

Creech, who has lived six times longer than projected, is something of a walking miracle.

"[Doctors] are always looking backwards to get their numbers and, at that point, they didn't have very far to look back so their numbers were very conservative," Creech said, in reference to his own projected survival with a donated



Ahmed Osama Gaber, M.D., is director of Houston Methodist J.C. Walter Jr. Transplant Center.



Randy Creech, walking a hallway at Memorial Hermann-Texas Medical Center, has been living with a donor heart for nearly three decades.

heart. “Now, doctors say different things, but they will say about 10 to 12 years for survival.”

Changing expectations

There is no particular, built-in time that a donated organ should stop working, said R. Patrick Wood, M.D., executive vice president and chief medical officer of LifeGift, the not-for-profit organ procurement organization that recovers organs and tissue for individuals needing transplants in Texas and beyond. The long-term survival rate, he added, varies from organ to organ.

“When I started in 1984, our expectation was that very few people [receiving donor organs] would survive,” Wood said. “That has completely changed and now the expectation is when a patient is transplanted, they will not only survive, but they will survive long-term and have an excellent quality of life. That is because of improvements in the surgery, but also because of improvements in the medication that prevents rejection.”

Still, there is a long way to go in terms of increasing the longevity of transplanted organs beyond 10, 20 and 30 years.

“This is one of the main reasons why we need

more research in transplantation,” Gaber said.

“In my opinion, the organ that we transplant is in a very unusual, hostile environment.”

Organs are typically harvested from people who have died from brain death—individuals who have fallen or been involved in car accidents. The organs are harvested from the donor’s body, put in a cooler, transferred by car or plane and then transplanted into a patient who is already compromised by their original disease. Once the organ is transplanted, the recipient’s immune system must cope with this foreign entity.

“The organ goes through a whole cycle of injury from the minute something happens to the donor to the end of the organ’s life in the recipient,” Gaber said. “It is not unusual, but it is actually a miracle that we get so much survival with these organs.”

Physicians discuss transplanted organs in terms of half-lives, meaning the point at which half of the transplanted organs have failed but the other half are still going strong. Calculating the life of a transplanted organ is a challenge because multiple factors contribute to how long a patient can live with a transplanted organ.

“We are not able to calculate the half-life of a

liver. It lasts longer than all of the other organs because liver cells regenerate,” Gaber said. “The half-life of a lung is shorter because it has many different elements and it is constantly exposed to the elements. It is in the vicinity of seven years. And the heart is in the teens—12 or so years.”

Doctors have found the best transplant results with living kidney donations.

“The half-life of a living donor transplant kidney is 21 years,” Gaber said. “If you take the same age donor and everything else from a cadaver kidney, the half-life is nine years.”

Behavior and adherence to a treatment plan also help determine how long a patient can live with a transplanted organ.

“It is important for the patient to understand that as soon as they get the transplant, they are getting a new disease,” Wood said. “If there was a disease that led them to getting a transplant, they now have a new disease and that is the transplanted organ. That organ requires monitoring basically indefinitely. The frequency of the monitoring decreases over time, but ongoing monitoring of the organ is imperative for long-term success.” ➡



Creech spends time visiting patients waiting for heart transplants and recovering from heart transplants.

Rejuvenate, resuscitate, regenerate

Today, Creech takes only one of the three immunosuppressant drugs typically given to transplant patients, but ever since he received his transplant, he has worked to adhere to the guidelines his doctors gave him.

"You are immunocompromised when you have a transplant and you have to be on guard about that," Creech said. "If a person who is

immunosuppressed gets a temperature or they have a cold, they can't just wait to see if they get over the cold. They have to call a doctor. In my experience, it is not that you catch so many infections or diseases, but the few you do catch, they can progress really quickly. I try to stay on top of all of that. ... If I have a temp or a sinus infection, I go to the doctor; I don't just think they will get better by themselves. Living with the immunosuppressant drugs, you have an increased risk of getting all kinds of things."

Because the immunosuppressant drugs are so toxic, they can lead to cancer, kidney failure and death in transplant patients.

"The great thing is, we can, through research, learn how to rejuvenate, resuscitate and regenerate these organs. That is really the new thing in transplantation," Gaber said. "We have so much happening in the lab. We are doing studies on using stem cells to rejuvenate these organs. We have tolerance studies in the clinic and in the lab where we are trying to get people to *not* take immunosuppression. We give them radiation and after six months, if they are still stable, you take them off the radiation. The radiation is supposed to prevent rejection."

In the nearly three decades since his heart transplant, Creech has seen both of his children graduate from college, receive graduate degrees,

marry and have children of their own. He and his wife, Linda, have traveled the state of Texas watching their seven grandsons compete in nearly every sport imaginable. Three of those grandsons have gotten married, so Creech is hoping for a great-grandchild soon.

He is often asked if he ever thinks about his heart transplant.

"Of course I think about it. And if I forget, I have an alarm that goes off every day to remind me to take my medicine," Creech said.

He has also devoted a lot of his time to visiting patients who are waiting for heart transplants and who have just received heart transplants.

"It means a lot to me to help these patients," Creech said. "It took me years to find my donor's family and now we send them flowers every year on the week their son died and we send them a Christmas gift every year. Perhaps, part of the reason I feel so attached to the family is that at the time of the accident, Aaron Stitt, my donor, had just finished his freshman year of college at Oklahoma State. He was 19 and he had so many parallels to my own son who was the same age and had just finished his first year of college."

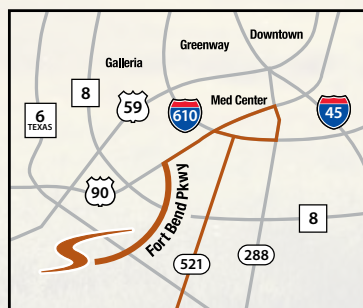
The donors are the real heroes, Creech said.

"Without them," he said, "none of us get to count years at all." ■



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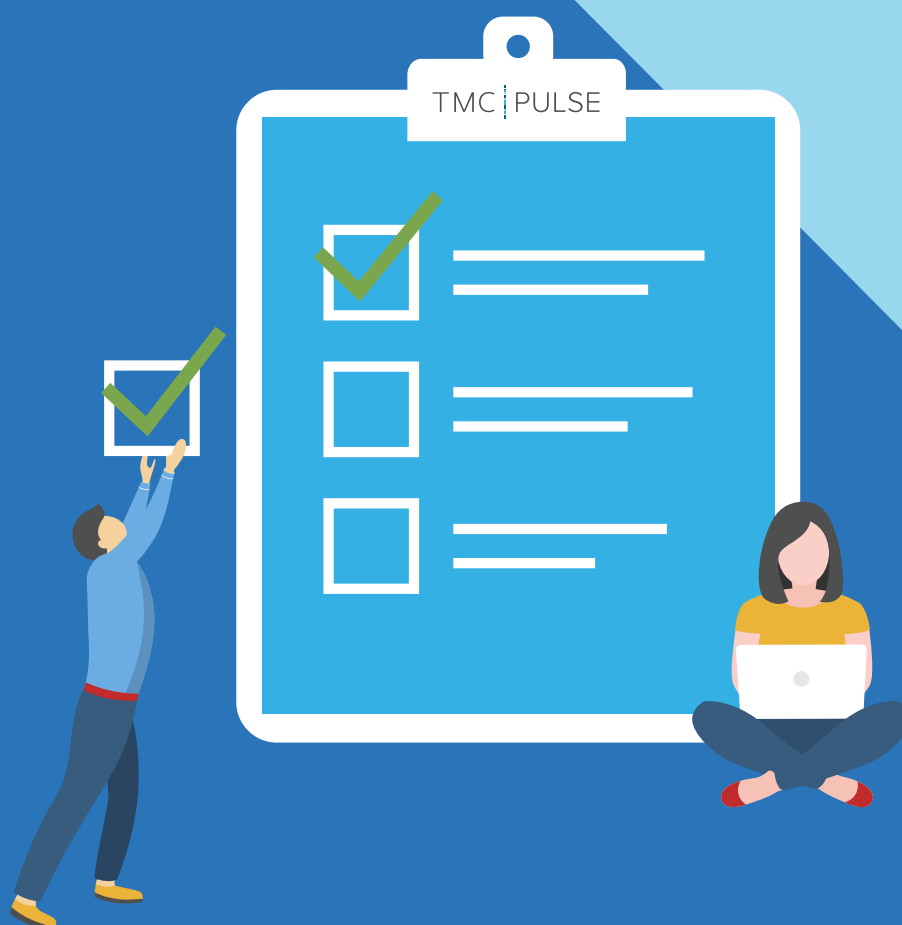
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The Face of Courage

Once known as the “woman without a face,” Carolyn Thomas helps other victims of domestic violence

BY SHANLEY PIERCE



In March, Carolyn Thomas visited reconstructive plastic surgeon Eugene Alford, M.D., who helped rebuild her face 14 years ago.

When Carolyn Thomas arrived at the office of Eugene Alford, M.D., for a preoperative visit, he greeted her with a warm embrace. She had driven three hours from her home in Waco, Texas, to see the reconstructive plastic surgeon, a dear friend and mentor.

Alford ushered Thomas into an exam room at the Houston Methodist Hospital Outpatient Center to inspect her face—a face he helped rebuild 14 years ago.

Thomas had an infection near her eye and Alford planned to fix the problem by replacing an artificial bone.

Sitting in an exam room, Thomas, 48, gently peeled off her

flesh-colored silicone prosthetic nose to reveal a deep chasm in the middle of her face—a hole where her nose used to be.

It was a stark reminder of the devastating, violent night in 2003 that earned her the epithet “woman without a face.”

‘He was really trying to kill me’

On Friday, Dec. 5, 2003, Carolyn Thomas’ then-boyfriend, Terrence Dewaine Kelly, entered her home in a drug-induced rage—yelling hysterically about someone being in the apartment.

Thomas and her mother tried to calm him down, but to no avail. He

pulled out a .44 Magnum revolver, shot first at the ceiling and then again into the floor of Thomas’ apartment. The second bullet entered the living room of Thomas’ downstairs neighbor, who immediately called the police.

Upstairs, Kelly shot Thomas’ mother in the abdomen. He dragged Thomas into the living room, held the gun to her head and pulled the trigger—shooting her in the face at point blank range.

“The way he held the gun, I think he was really trying to take my life,” Thomas said. “I don’t think he was just trying to mess my face. He was really trying to kill me.”

The two met through a mutual

friend in 1992 and started dating shortly afterward. There were warning signs early on; he was controlling and didn’t want her hanging out with certain people or dressing a certain way.

Three years into their relationship, Kelly physically assaulted Thomas for the first time. Violence and death threats continued over several years, culminating in that tragic December day.

Leading up to the shooting, Kelly had smoked a “wet” cigarette made of marijuana soaked in embalming fluid, Thomas said, which can cause hallucinations, disorientation, impaired coordination, paranoia and visual disturbances.



“ I used to ask my nurses, ‘Why did God leave me here?’ I think He left me here to save more lives, to be a visual aid. I’m not saying emotional or mental abuse is any different than physical abuse, but with physical abuse ... you see this person with just one working eye. You see this person with a prosthetic nose. You see this person who lost 80 percent of her face. ”

“I was contemplating, ‘Well, did he do this because he smoked a drug and he was hallucinating? Or did he do this because that’s what he said he was going to do over the years?’” she said. “I finally came to the conclusion that that’s what he

wanted to do.”

When first responders arrived at the blood-spattered apartment, Thomas’ mother, Janice Reeves, was still alive and urged the paramedics to take care of her daughter first. Reeves died later that night, the

bullet in her abdomen causing irreparable damage to her organs.

At the local hospital, doctors were able to stabilize Thomas and stop the bleeding from her face. Thomas remembers a nurse coming into her room to clean out her

wounds. The nurse asked Thomas if she wanted the two people in the room to leave, but Thomas—who did not fully understand the severity of her injury—allowed them to stay. As the nurse carefully unraveled the bandages wrapped around Thomas’ face, everyone in the room gasped.

“Then I knew it was bad,” Thomas said.

The gunshot blast decimated Thomas’ face. She lost her right eye, nose, upper top lip and most of her left side. Virtually 80 percent of her face was gone. ➡

— CAROLYN THOMAS

Domestic violence awareness advocate

The 10-foot test

Terrence Dewaine Kelly was sentenced to life in prison in April 2005. At that time, Thomas was wearing bandages around her face to hide herself from the world—only cutting out a tiny eye hole on the left side to see. Going out in public was an emotional roller coaster.

“I scared a lot of kids,” Thomas said. “I would be in the airport and people would stop and point. ‘Oh my God, you don’t have a nose!’ It was really rough at first. People would just look at me.”

Alford first examined photos of Thomas in 2004. As a member of Face to Face, a national organization that helps domestic violence victims receive free reconstructive plastic surgery, he was asked to review Thomas’ case after plastic surgeons in Waco and Dallas declined to operate on her.

“This is a person who had suffered greatly and she needed—as lots of survivors of domestic violence need—medical help and counseling,” Alford said. “Every survivor of domestic violence



Thomas and Alford embrace during a pre-op visit in March.

suffers, but she had suffered more than most.”

Alford knew from the start that he and a multidisciplinary team from Houston Methodist and The

University of Texas MD Anderson Cancer Center had a herculean task ahead of them. He had operated on domestic violence survivors in the past, performing cosmetic surgeries

to “take away the reminders” of the trauma, but none of the patients was as badly damaged as Thomas.

Over the course of 17 months, Thomas underwent 12 surgeries. She would never look the same again, but she would at least be able to pass what Alford referred to as the “10-foot test.”

“I would look normal to everybody, but if you’re up close, then you’d notice that I had surgery,” Thomas explained.

Alford took bone from Thomas’ right fibula and molded it to create an upper jaw. Then, he used a flap of skin and the connecting blood vessels from the same leg to build the roof of her mouth and gums and blanket the gaping hole in her face. Muscle from the side of her head was transferred to pull up the corner of her mouth.

“There are parts of the body that are meant to be used as spare parts,” Alford said. “The middle three-quarters of the fibula has no function. It doesn’t bear weight. It doesn’t do anything. You need your fibula at the knee and at the ankle

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for stability, but the rest of the bone in the middle is a spare part. I use cartilage from the ear and the rib every week as spare parts to rebuild parts of the nose and face.”

Anaplastologists from MD Anderson’s Head and Neck Center were recruited to help with the last piece of the puzzle: Thomas’ nose. The team pored over photographs of Thomas before the shooting and sculpted six models before recreating a silicone nasal prosthesis that closely resembled her nose.

After her surgery, Thomas appeared on “The Oprah Winfrey Show,” “Larry King Live” and the 2006 Discovery Health Channel documentary “Plastic Surgery Before and After: Reconstructing Carolyn Thomas.” She became known nationally as the “woman without a face,” but has since fought for a new identity as the face of domestic violence to help other women in abusive relationships.

In May 2006, Thomas founded Voices 4 All: The Carolyn Thomas Foundation to spread awareness and support victims and survivors of

domestic violence.

Thomas considers herself a “visual aid” for her cause.

“I used to ask my nurses, ‘Why did God leave me here?’ I think He left me here to save more lives, to be a visual aid,” she said. “I’m not saying emotional or mental abuse is any different than physical abuse, but with physical abuse ... you see this person with just one working eye. You see this person with a prosthetic nose. You see this person who lost 80 percent of her face.”

One in 4 women and 1 in 7 men have been victims of severe physical violence by an intimate partner in their lifetimes, according to the National Coalition Against Domestic Violence. On average, nearly 20 people per minute are physically abused by an intimate partner in the United States—more than 10 million women and men per year.

‘I just don’t take any BS anymore’

Thomas is still in awe of her reconstructed face 16 years later. Seeing

pictures of herself before the surgery still brings tears to her eyes.

“I just can’t believe how far medicine and science have come. They put 80 percent of me back together—whether it’s a prosthetic nose or a prosthetic eye,” Thomas said. “They put Humpty Dumpty back together again.”

But because surgeons put her back together with artificial materials and parts of her own body that are also subject to age and wear, Thomas knew she would need retouching every 10 to 15 years.

Her recent pre-op visit to Houston Methodist was for the first touch-up surgery since 2006. She likely will require additional procedures in the future.

Because the mucus secretion from her nasal sinus cavity sits in close proximity to her eye, the artificial bone used to create the shelf of her orbital bone had become infected and needed to be replaced with new artificial bone.

“We knew that from the start with Carolyn,” Alford said. “The hospital didn’t just buy into a series

of surgeries. They bought into a lifetime of care for her.”

Alford is proud of his patient, proud that she turned her pain into a source of inspiration for others.

“She’s actually thriving as a community advocate, being an example of what can happen if you don’t take charge of your life and do the right thing when it comes to dealing with domestic violence,” he said.

Although Thomas still mourns the loss of her mother and will never forget the shooting, she faces the world with optimism and purpose.

“It made me courageous in a way. I’m stronger than I thought was,” she said. “When I was in relationships with Terrence, he could just run over me and tell me what to do. But now, after going through the surgeries and having conversations with Dr. Alford and people who are positive, I just don’t take any BS anymore. ... I am beautiful inside and out.” ■

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Must-Have Medicines for Kids with Cancer

Clinical experts argue for an essential medicines list for pediatric cancer patients to address chronic shortages

BY ALEXANDRA BECKER

Imagine that a child is diagnosed with cancer. Now, imagine that the lifesaving chemotherapy drugs needed to treat that child are in short supply—and for simple, fixable reasons.

It's a reality playing out in hospitals across the United States and researchers at Baylor College of Medicine have a solution. In a recent position paper published in the journal *JAMA Pediatrics*, Stacey Berg, M.D., and Brooke Bernhardt, Pharm.D., called for the development of an essential medicines list for pediatric oncology. Modeled after the World Health Organization's own Essential Medicines Lists—recommendations that cover the gamut of conditions for both children and adults—theirs is a straightforward call to address what has become an increasingly frequent obstacle to care.

“One of the things that was really appalling when we were working on the paper was how many drugs we use all the time that turned out to be in short supply some time in recent history—I was shocked,” said Berg, a professor and associate dean for research assurances at Baylor College of Medicine.

The reason these drugs are growing scarce is complex, she said.

“For some drugs, the issue is difficulty manufacturing them, or difficulty with supply or with the FDA [U.S. Food and Drug Administration] inspections of the plants. But really, I think the bottom line is economics—not at the level of individual drug companies, but at the level of what we, as a society, say is worth a lot of money,” explained Berg, who is also co-director of Texas Children's Cancer Center's Developmental Therapeutics Program. “Old, generic drugs—even though they are essential to treatment of all kinds of health issues—they don't make a lot of money for people.”

But when it comes to pediatric oncology, old, generic drugs are the cornerstones of treatment.

“One of the reasons that we use old drugs in pediatric oncology is because many of them work great,” Berg said. “Adult oncology tends to use many newer, more expensive drugs because nothing that they've ever had worked, whereas in pediatric oncology, there have been increasing cure rates for children with cancer since the early '70s. Many of our treatments today are still based on those treatments, and it's not because the field hasn't advanced, it's because the treatments are very good and you don't want to go away from



Stacey Berg, M.D., and Brooke Bernhardt, Pharm.D., want to model an essential medicines list for pediatric oncology after the World Health Organization's own Essential Medicines Lists.

“In general, you don't hear about shortages of new drugs for very long. What you hear about is the shortages of old drugs that don't have patent protection anymore.”

— STACEY BERG, M.D.

Professor and associate dean for research assurances at Baylor College of Medicine

things that work so well.”

New, cutting-edge drugs are continuously being added to therapies to improve outcomes and, as Berg and Bernhardt pointed out, they make manufacturers a nice sum of money and are rarely in short supply.

“In general, you don't hear about shortages of new drugs for very long,” Berg said. “What you hear about is the shortages of old drugs that don't have patent protection anymore.”

Bernhardt, an assistant professor of pediatrics in the hematology and oncology department at

Baylor, illustrated the issue with numbers.

“The new drugs that can charge \$70,000 and up a dose, of course they're going to make those drugs,” she said. “The drugs that are \$2.15 a vial, that's a little bit more challenging.”

Inferior outcomes

Baylor and Texas Children's have set procedures in place to ensure these shortages don't affect patient outcomes, but it's no easy feat. ➡

“When I’ve spoken with drug companies, the gap is with them understanding what the demand is in order for them to make the right amount and for them to know that they’re going to have purchasers of that product.”

— BROOKE BERNHARDT, PHARM.D.

Assistant professor of pediatrics in the hematology and oncology department at Baylor College of Medicine

“It’s a chess game,” Berg said. “If there is a shortage of something important, we spend a lot of time moving the pieces so that the patients don’t get affected.”

Texas Children’s has a team ready to make moves when necessary, but not all hospitals have those resources.

“It’s a lot of manpower and it takes a lot of work and a lot of people,” Bernhardt said. “So there’s a lot of interest in coming up with early detection—how, on an institutional level, you can prevent and mitigate the risk to patients.”

Those risks can manifest in delayed administration of lifesaving therapies and, in at least one published case, inferior outcomes.

In a 2012 paper published in the *New England Journal of Medicine*, researchers found that an alternative treatment for pediatric patients with Hodgkin’s lymphoma resulted in a decreased survival rate. Specifically, when mechlorethamine

(Mustargen) supplies ran short, the clinicians switched to the drug cyclophosphamide (Cytoxan) because the medications were supposed to be interchangeable. But Cytoxan was only associated with a 2-year event-free survival rate of 75 percent, as opposed to an 88 percent survival rate with Mustargen.

“No one wants to say, ‘We can’t provide our patients with the very best care,’ so people are leery of raising the issue,” Berg said. “It’s really like any other safety concern. Until you are able to be transparent about what the risks are, you can’t make it any better.”

And this problem isn’t limited to pediatric oncology.

“We see it in critical care, pain management, OB-GYN,” Berg said. “You could find other shortage stories around the medical center of other kinds of drugs where you would say, ‘Are you kidding me?’”

Supply and demand

The list proposed by Berg and Bernhardt includes approximately 40 anticancer drugs and 35 supportive care medicines, Berg said. Not all are in short supply, but all are medicines the researchers believe to be essential to a hospital or clinic treating pediatric cancer patients. Their hope is that the list can begin a conversation about shortages and incite policy or industry change that would ensure reliable access to these drugs and forecast shortages far in advance.

“It wasn’t our goal to make the ultimate list. It was to show what it would look like as a starting point,” Berg explained. “The list by itself doesn’t do anything except draw attention, but I think underpinning the idea of the list is the concept that health care, and therefore cancer care, is a right and should be available to everybody.”

So how could institutions or policymakers put that into practice?

“Right now, there is no mechanism. There’s no rule that says a company has to make a drug and there’s really no rule that says the company has to tell you when you’re going to run out,” Berg said.

Bernhardt said her hope is that manufacturers would work harder to track demands for certain drugs and respond with a more coordinated system for ensuring their output meets those demands.

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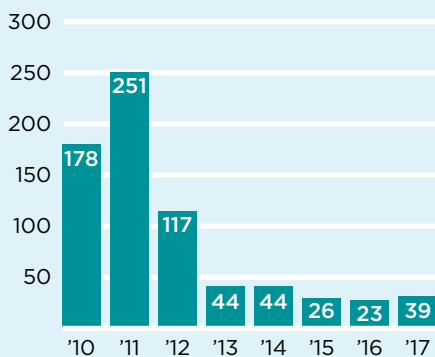
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“When I’ve spoken with drug companies, the gap is with them understanding what the demand is in order for them to make the right amount and for them to know that they’re going to have purchasers of that product,” Bernhardt explained. “If there are 20 companies out there and they’re all making thioguanine, and they’re all making enough for 18,000 children, well that’s too much—we don’t have that many kids with leukemia every year. A perceived surplus may then drive a reduction in production, which can result in shortages. We have to find a way to match the demand with the supply so that we can come to a better price point, which will drive manufacturing.”

If hospital associations provided data to help create forecasting models, Bernhardt said, that information could be shared with regulatory bodies and manufacturers to create a system based simply on supply and demand.

“When you think about countries overseas who say that certain drugs are on their essential medicines lists, they’re taking another step and saying, ‘How much do we have to budget to pay for those drugs?’” Bernhardt said. “That’s something that we haven’t really done as a country because we have so many private pay, cash pay, third-party payers. And when you look at something like CMS [Centers for Medicare & Medicaid Services], a good question to ask is how we can

NUMBER OF NEW DRUG SHORTAGES PER YEAR, 2010 – 2017



FDA's Center for Drug Evaluation and Research

Source: FDA "Report on Drug Shortages for Calendar Year 2017"

leverage our regulatory framework to help drive manufacturing.”

Legislation likely would be necessary, as well, Berg added.

“I don’t think pharma companies are evil, but they have certain responsibilities that are economic,” she said. “I think we need to make some incentives and maybe some regulation that spreads that burden in some reasonably fair way across the pharmaceutical landscape.”

The supply-and-demand model has worked well for other areas of medicine. The Centers for Disease Control and Prevention works with a multidisciplinary group called the Advisory Committee on Immunization Practices to develop recommendations related to vaccines. Each year, manufacturers can adjust production of the influenza vaccine based on models and predictions for the upcoming flu season.

“This group helps estimate how much vaccine will be used so that the companies know how much to produce,” Bernhardt said. “There’s an expected demand and then there’s a supply that’s produced in anticipation of that demand.”

The problem has a solution, Berg said, but it’s a matter of whether voters, policymakers and institutions are willing to address the underlying issues that are creating these shortages.

“We really need to think in this country about health care and whether we want to be able to say that everybody can get it or not,” she said. “If we say, ‘You know what, we’re just *not* going to guarantee as a country that every kid with cancer can get adequate treatment’—I don’t know anybody who would be very comfortable saying that that’s our national choice. But the decisions that we make about insurance and payment and drug pricing—those decisions are also making that decision.” ■



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Five Ways to Eliminate HIV in the Next Decade

Infectious disease expert Charlene Flash, M.D., weighs in

BY BRITNI R. MCASHAN

1 IDENTIFY

The first thing we need to do is identify people. **Can we identify people who have HIV? Yes.** We have excellent HIV testing platforms, but are we actually testing all of the people who should be tested? No.

2 PREVENT

Do we have the tools so we can prevent someone who is not HIV positive from getting infected? Yes, we do. We used to only be able to tell people to screen blood supply, use condoms and you'll be fine. And we realized that sexual behavior is very hard to control and just a condom policy wasn't working to decrease the numbers of new infections. But now we have a daily pill called PrEP—one tablet once a day to protect people who are vulnerable to HIV from becoming infected.

3 MAINTAIN

Once you identify someone who is HIV positive, do we have the tools we need to get the virus under control rapidly so it never progresses to AIDS? Absolutely. We have several one-tablet once-a-day regimens for HIV that work quickly and are easy for patients to take, in terms of low side effect profile. So not only does that help people not progress to AIDS, but by getting their HIV under control, it actually makes them less infectious. So when I help this person, I help get their infection under control, but I also protect them from infecting their sexual partners and loved ones and their community.

4 DESTIGMATIZE

We need to work toward making sure that we are doing broad HIV testing, just testing everyone. Years ago and even now, there has been so much stigma around getting tested. What would be more destigmatizing than saying this is a test that everyone gets. It's not because of your sexual identity or because I think you are a loose woman. It's not because of the color of your skin or how much money you make or where you live, but just that we test everyone. That would go a long way to decrease stigma and it would go a long way to make sure we are not missing anyone who is infected. **We need to make sure clinicians are testing patients, that patients are able to access testing even outside of clinical environments and that it is not a scary thing—that it is just part of something you do, like getting your blood pressure checked.**

5 PROVIDE ACCESS

We need to make sure the tools are available to whomever needs them—regardless of where they live, whether they are insured or not insured, whether they have a car or not, whether they are in an urban area or a rural area. We just need to make sure people can access these tools. We have great drugs, but we still have people who either don't have access to a clinician to get medication or, once they get access to a clinician, there are so many barriers to getting on medication, they don't. Even for insured people there can be barriers—high co-pays and prior authorizations and all of these things that prevent people from getting what they need. If we work to eliminate these barriers, we can get there.

During his State of the Union address in February, President Donald Trump promised to “eliminate the HIV epidemic” in America within 10 years.

HIV is the human immunodeficiency virus that can cause acquired immune deficiency syndrome, or AIDS. Since the beginning of the epidemic in 1981, more than half a million people in the United States have died of AIDS. But in recent years, because of new medications and preventive treatments, many of the estimated 1.1 million people in the U.S. living with HIV have been able to enjoy a better quality of life. A diagnosis is no longer a death sentence.

“In the United States and around the world, the tools [to fight HIV] are available, so it's not that there is a ‘secret sauce’ or some science that we have not yet discovered,” said Charlene Flash, M.D., an infectious disease expert and associate chief medical officer at Legacy Community Health.



“We have the tools, so the real challenge is: Do we have the political will, the applied funding, the attention to the nuances to be able to implement those tools in the spaces where they are going to make the most difference so we can actually end the HIV epidemic?”

Ironically, in cities such as San Francisco and New York, where the autoimmune disease was highly concentrated for a long time, new infection rates have dropped dramatically and many people living with HIV have achieved viral suppression. But in the South, rates of new infections are still rising among some populations.

“A lot of the attention and political will occurred on the coasts,” said Flash, a clinical assistant professor at Baylor College of Medicine. “We used to think of HIV as the gay-related infectious disease, so areas in the country where people rallied around their brothers and sisters infected with HIV were also areas that were ‘safe spaces’ to express your sexual identity. Even though the initial cases were identified on

the coasts, a shift happened and we started to realize this wasn’t something that was gay-related. ... We realized that anyone who had an exposure could be infected. But initially, perhaps, we weren’t paying attention. Part of what happened in this space of not paying attention is people from other communities were getting infected and folks weren’t noticing.”

Now, Flash said, we have to be innovative and creative to end the HIV epidemic—in the South and elsewhere.

“Ten years is a long time when you have the tools,” she said. “It is really an implementation challenge. The worst thing someone can say to me is, ‘That’s the way we have always done it.’ That is the very best way to get Charlene Flash going. We cannot tolerate complacency for something that is so important. We can’t rest on how things have always been done. We have to challenge that mantra and we have to ask, ‘What will our future be?’” ■

“ In the United States and around the world, the tools [to fight HIV] are available, so it’s not that there is a ‘secret sauce’ or some science that we have not yet discovered. We have the tools, so the real challenge is: Do we have the political will, the applied funding, the attention to the nuances to be able to implement those tools in the spaces where they are going to make the most difference so we can actually end the HIV epidemic? ”

— CHARLENE FLASH, M.D.

Associate chief medical officer at Legacy Community Health and clinical assistant professor at Baylor College of Medicine



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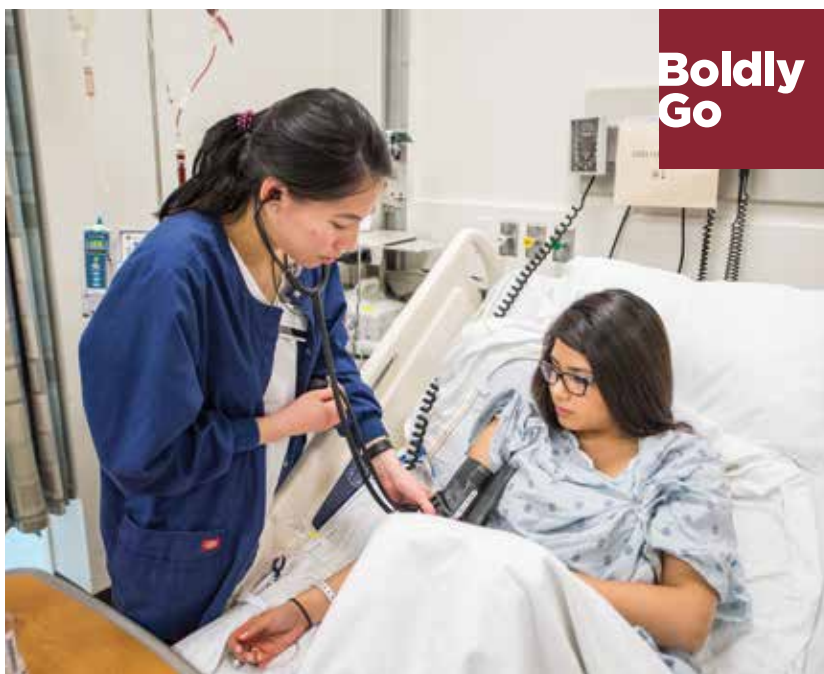
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TEXAS WOMAN'S
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1 | Houston Texans wide receiver, Deandre Hopkins, left, went out for a pass from patient Greg at the National Pediatric Cancer Foundation's Fashion Funds the Cure event at The Galleria. Patients from **THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER, CHILDREN'S MEMORIAL HERMANN HOSPITAL** and **TEXAS CHILDREN'S HOSPITAL** walked the runway with adult professionals who hold jobs they admire.

2 | **BEENA GEORGE, PH.D.**, will become Chief Innovation Officer of the University of St. Thomas (UST) in July. Currently, she is dean of UST's Cameron School of Business.

3 | **JEREMIAH JOHNSON, M.D.**, assistant professor of neurosurgery at Baylor College of Medicine, was a recipient of a 'Houston Knuckleball' Patients' Choice Award from the Joe Niekro Foundation, which funds research, treatment and awareness of brain aneurysms, arteriovenous malformations and hemorrhagic strokes, and provides patient and family support. The award was founded in honor of former Houston Astros pitcher Joe Niekro, known for throwing a knuckleball pitch, who died of a brain aneurysm in 2006.

4 | The Medical Towers Building at 1709 Dryden will be restored by Pearl Hospitality to become the **WESTIN HOUSTON MEDICAL CENTER**. Redevelopment of the 382,000 square foot midcentury landmark will preserve the building's historic integrity and update the space for contemporary needs. Opening is slated for early 2020.

5 | Brad Ellington, Shawn Stoute, John Whittle, David Carmony and **RONALD McDONALD HOUSE HOUSTON (RMHH) CEO RICK NORIEGA** pose at the RMHH Cup Golf Tournament, which raised more than \$335,000. Proceeds will support the nonprofit's mission to serve families of children with life-threatening illnesses receiving treatment in the Texas Medical Center.



Credit: Nos. 2, 3, 5, 6, 7, 10, 11, 12 courtesy photos; No. 4, courtesy of Pearl Hospitality; No. 8, Daniel Ortiz; No. 13, David Braun Photography



6



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6 | CARLA DAVIS, M.D., chief of immunology, allergy, rheumatology and retrovirology at Texas Children's Hospital and associate professor of pediatrics at Baylor College of Medicine, was named an at-large director by The American Academy of Allergy, Asthma & Immunology.

7 | WILL PARSONS, M.D., PH.D., was named deputy director of Texas Children's Cancer and Hematology Centers. Parsons also serves as co-director of the Brain Tumor Program, co-director of the Cancer Genetics and Genomics Program, and director of the Center for Precision Oncology within Texas Children's Cancer Center.

8 | Houston Hospice's Butterfly Luncheon chairs Isabel Lummis, Sue White and Jenny Kempner address guests at the Junior League of Houston. Proceeds help fund **HOUSTON HOSPICE** operations and its Butterfly Program of pediatric hospice care.

9 | The **TEXAS MEDICAL CENTER POLICE** have relocated to a new headquarters at the corner of Bertner Avenue and Holcombe Boulevard. The new location brings the TMC Police into the core of the medical center to better serve the growing TMC community.

10 | Brianna Mathis and Laura Arredondo interact at the new community health center on the **UNIVERSITY OF HOUSTON** campus. The clinic is located in the Health 2 Building, temporary home of the planned UH College of Medicine, and features 12 exam rooms and another 15 rooms for behavioral health services.

11 | CHARLES MOUTON, M.D., has been appointed executive vice president, provost and dean of The University of Texas Medical Branch at Galveston School of Medicine.

12 | CHERYL WALKER, PH.D., director of the Center for Precision Environmental Health and professor of molecular and cellular biology at Baylor College of Medicine, was honored with the Society of Toxicology's Distinguished Toxicology Scholar Award.

13 | Maternal-fetal medicine specialist **KENNETH MOISE, M.D.**, left, who received the Society for Maternal-Fetal Medicine's Lifetime Achievement Award, posed with Sean C. Blackwell, M.D., chair of the OB-GYN department at The University of Texas Health Science Center at Houston's McGovern Medical School.

Do you have TMC photos you would like to share with *Pulse*?
Submit high-resolution images to: news@tmc.edu

May 2019

5/2

Art with Heart

San José Clinic's annual event honors volunteers

Thursday, 6 – 10 p.m.

The Ballroom at Bayou Place

500 Texas Ave.

Tickets start at \$175 and can be purchased at sanjoseclinic.org

cristinaherrera@sanjoseclinic.org

713-490-2620

5/7

Research Day

UTMB Health offers lectures, breakout sessions

Tuesday, 8 a.m. – 4 p.m.

UTMB Campus

Levin Hall

1006 Market St.

Galveston, Texas

Register at research.utmb.edu/researchday

resday@utmb.edu

409-266-9432

5/13

Nursing Open House

Monday, noon – 1 p.m.

Prairie View A&M University College of Nursing

6436 Fannin St.

fdsmith@pvamu.edu

713-798-6590

5/30

Grand Rounds

*Houston Methodist DeBakey Heart and Vascular Center
grand rounds featuring Yang Zhan, M.D.*

Thursday, 8 – 9 a.m.

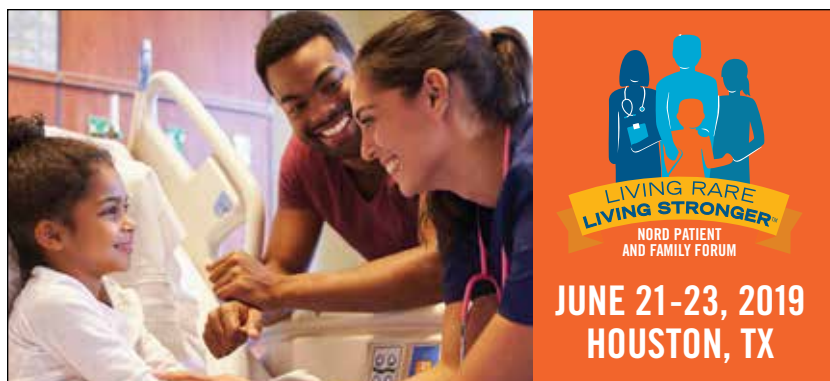
Houston Methodist Hospital

Dunn Rio Grande Conference Room

6565 Fannin St.

tbarsamian@houstonmethodist.org

346-238-5391



JOIN US FOR A RARE WEEKEND. LEARN & CONNECT IN HOUSTON!

WHY SHOULD MEDICAL PROFESSIONALS ATTEND?

Patients with rare diseases present unique challenges to their medical caregivers. The **2019 Living Rare, Living Stronger NORD Patient and Family Forum** is an annual conference that presents a unique opportunity for connecting to the rare disease community. You will learn how to:

- Help patients when you are not specialized in a particular rare disease
- Address the psychological impact of a rare disease
- Reduce delays in diagnosis
- Secure career/funding opportunities related to rare disease research



Learn more and register at:
rarediseases.org/living-rare-forum

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Level

1

Ours is one of only two Level I trauma centers in this region. And that's as critical as the care we deliver. Trauma patients simply have better odds at a Level I trauma center than a Level II. So when someone's life is at stake, we want to give that person the best possible care. **Trauma is our thing.**

Trauma
Center

Ben Taub Hospital

Ginni and Richard Mithoff Trauma Center

HARRISHEALTH SYSTEM harrishealth.org

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Colleen Sherlock, 713.858.6699



Sheridan
Rice/Museum District, \$2.2+ mil.
Amy Johnson, 832.541.4805



Berthea
Rice/Museum District, \$1.9+ mil.
Tim Surratt, 713.942.6830



Berkshire
Bellaire, \$1.6+ mil.
Bonnie Laughlin, 713.805.6422



Mimosa
Bellaire, \$1.4+ mil.
George Sutherland, 713.942.6891



Bissonnet
Rice/Museum District, \$1.2+ mil.
Heidi Dugan, 713.725.9239



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