When I introduce myself to Dr. Billy Cohn, our conversation takes an unexpected turn. Instead of exchanging the usual pleasantries about the weather, he focuses immediately on my name.

“Dayton? Like the town in Ohio?” he asks.

“That’s it,” I confirm.

“That’s the home of the Wright Brothers—they’re relevant to our conversation, you know.”

At this, I express some surprise. Cohn is, after all, a surgeon, and he serves as the director of minimally invasive surgical technology for the Texas Heart Institute at Houston’s St. Luke’s Episcopal Hospital. Since we’re meeting to discuss his role in creating a new generation of artificial hearts, I don’t immediately see the relevance of the Wright Brothers. Cohn explains.

“There are some wonderful parallels between the evolution of this field of artificial hearts and the evolution of heavier-than-air flight,” he says. “In the early days of work on manned aviation, all of the people involved tried to copy the mechanism of flight that they observed in the natural world—strong wings, and a mechanism to flap them.” While this approach worked well for bats and birds and butterflies—creatures that could heal and regenerate damaged tissues—man-made components were far less durable. “It was only when they abandoned the idea of flapping wings, and came up with the idea of a rapidly spinning propeller, that heavier-than-air flight became a practical reality.”

Cohn believes that a similar problem has stymied efforts to create a truly practical replacement for the human heart. Researchers, he says, have focused too narrowly on creating devices that mimic the heart they’re trying to replace. Healthy human hearts fill up with blood, then pump it through the body at a rate of around 60 beats per minute. That adds up to tens of thousands of heartbeats each day and more than 31 million each year. The mechanical hearts developed in the last 40 to 50 years function very much like the healthy hearts they replace, with bladders, valves and pusher plates replicating the activity of a healthy heart. That these devices work at all is amazing, but man-made materials just aren’t as resilient as healthy heart tissue; they succumb to cyclic fatigue and mechanical failure. At best, these mechanical hearts function as a bridge to a transplant—if a transplantable heart can be found in time.

Like the Wright Brothers before them, Cohn and his colleagues at the Texas Heart Institute have decided that finding the answer to this challenge requires a change of perspective. Instead of building a machine that beats like a heart, they
are developing a new generation of devices that use spinning turbines to push blood through the body continuously, eliminating the heartbeat altogether.

This is a remarkable conceptual leap. The very notion of life going on without a pulse runs counter to our understanding of the natural order of things. But this willingness to consider unconventional solutions to long-standing challenges is a driving force in the effort to rein in costs and improve the quality of health care delivery in hospitals and clinics around the world.

The layman’s tendency, of course, is to focus primarily on whiz-bang technology for the answer to persistent health problems. The increasing pace of technical innovation is indeed a crucial element in the effort to create new treatments and better approaches to diagnosing and preventing disease. Incredible advances in nanotechnology, wireless communications, imaging technology and micro-processing power—all of which are intimately interrelated—have laid the groundwork for revolutionary advances in health care delivery. But progress in the field of medicine relies on more than technology: It relies as well on the increasing willingness of researchers such as Billy Cohn to break out of their so-called silos, interact with experts from a wide variety of disciplines, and move beyond preconceived notions about how things are supposed to work.

For Cohn and his colleagues, the inspiration for their pulseless mechanical heart can be traced back almost 40 years, to a chance observation made on a riverbank in rural Egypt. “Our good friend Rich Wampler is a general surgeon, but he’s also an inventor and engineer,” Cohn says. “He saw two Egyptian workers using an Archimedes’ screw—a long pipe with a spiral piece of wood in it—to pump water up a riverbank. As they rotated the tube, it pulled the water up. And Rich said, ‘Wow, if you can use a spinning spiral to move water against gravity, I bet you could use it to move water against pressure.’”

Since moving liquid against pressure is essentially what the heart does, Wampler connected the dots and designed a simple device that could be used to assist weak and damaged hearts. “Rich went back and designed a device, a little turbine about the size of a pencil eraser at the end of a tube the size of a soda straw,” Cohn says. “The turbine was powered by a spinning cable, like a speedometer cable, that was threaded up the patient’s leg.”

Wampler took the device to Cohn’s mentor, O.H. “Bud” Frazier. He convinced Frazier that this turbine, spinning at 25,000 revolutions per minute, could take the oxygenated blood normally pumped by a damaged left ventricle—the heart’s main pumping chamber—and pump it into the arterial system. The device wasn’t an artificial heart per se; the natural heart would remain in place, with the right ventricle continuing to do its job of pumping venous blood into the lungs to be oxygenated. Thus the heart would still beat, but the spinning turbine would relieve much of the strain on the left ventricle, the hardest working of the two chambers.

Although Frazier was skeptical at first—he was particularly concerned that the turbine would act like a blender, shredding the blood cells as they passed through it—he agreed to test Wampler’s device. After testing prototypes and finding that blood cells could indeed withstand the turbine’s shear, the researchers began testing the device in humans in the mid-1990s.

Today, these devices—known as left ventricular assist devices (LVADs)—are commonly used as a treatment for advanced heart failure. More than
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15,000 patients, including former Vice President Dick Cheney, have had them implanted, and Cohn notes that many U.S. patients have survived as long as eight years after receiving the implant.

This is good news for patients whose hearts are damaged but still have one functioning chamber. For those who have two damaged chambers, however, the alternatives are still limited to transplants, which are difficult to come by given the paucity of donor hearts; or a temporary mechanical device powered by a small compressor outside the body, such as the SynCardia, a direct descendant of the Jarvik-7—for now. Cohn and his associates believe that the same technology that powers the LVADs can be used to create a mechanical heart that will function not as a bridge to transplant, but as a durable alternative that will replace the damaged heart altogether. And, Cohn reports, they are indeed making significant progress in their quest.

Initial testing proved favorable, and in March 2011, Cohn and Frazier implanted an early version of the twin turbine device in a terminally ill patient. Cohn says that the prototype was cobbled together in his garage, “like the Wright flier,” and the patient did live on for five weeks, dying ultimately of unrelated causes.

Today, Cohn and Frazier are attempting to push this technology to the next level. The device used to keep the patient alive consisted of two turbines—Archimedes’ screws, suspended from both ends by bearings, spinning rapidly on axles. It had fewer moving parts than traditional mechanical hearts, to be sure, but was still susceptible to mechanical wear. So, pushing forward with a team of Australian engineers who are specialists in magnetic levitation and drive systems, Cohn’s team has designed a new device that consists of a disc that floats in a magnetic field. As it spins, blood on one side of the disc is pushed out through the body. The blood on the other side of the disc is pumped to the lungs. This past July, the team began advanced testing of the device, and Cohn believes it’s possible that the first pilot test on a human may take place in three or four years.

“It’s an artificial heart with one moving part that automatically balances the flow to the lungs and to the body,” Cohn says. “It’s a beautiful piece of technology and may very well be the first practical mechanical replacement for the failing human heart.”

**Nanosponges**

At the University of California, San Diego, Liangfang Zhang, associate professor in the Department of Nanoengineering and the Moors Cancer Center, is taking a similarly unconventional approach to a long-standing medical challenge. For Zhang, the challenge is toxins.

Toxins come from a variety of sources—bacterial infections, spider bites and so on—and they can be treated. But treating them requires identifying the antiserum, monoclonal antibody or small-molecule drug inhibitor that will attack and neutralize the particular toxic protein.

“These agents all target specific toxins,” explains Zhang. “They recognize the molecular structure of the toxin and then they neutralize it.”

This specificity is good, as long as physicians can pinpoint where the toxin came from. Was it a snake? A spider? Something that entered the body through an open wound? Without knowing the source of the toxin, it can’t be treated using traditional antitoxins.

Zhang’s solution to the problem of antitoxin specificity is something he calls a “nanosponge.” Toxins do their damage by tracking down and inserting themselves into a wide range of host cells, including red blood cells. After the toxin punches through the cellular membrane, the membrane becomes porous and the blood cell collapses. The key here is the membrane, Zhang notes.

Markers on the surface of the membrane identify it as a red blood cell. When the toxins “see” these markers, they attack. The nanosponge takes advantage of the fact that toxins are attracted to these markers, whether or not the mem-
“In a sense, the tumor cell never expects what’s coming. It doesn’t have the ability to defend itself against this new immune system.”

brane encloses an actual blood cell.

“The sponge is made of two parts—a core and a shield,” says Zhang. “The core is a polymer that has already been approved for use in humans by the FDA. This core is surrounded by a natural red blood cell membrane.”

The nanosponge, then, serves as a sort of decoy. The membrane’s markers identify the sponge as a red blood cell, so the toxins attack it as they would a normal red blood cell. The polymer core, however, prevents the sponge from collapsing. Thus, each sponge can absorb hundreds of toxin molecules. And because the sponges are small—each is roughly three orders of magnitude smaller than an actual red blood cell—a very large number of sponges can be injected into the patient’s bloodstream, vastly reducing the chances that real red blood cells will be targeted.

“We inject this army of nanosponges into the bloodstream,” Zhang explains. “Because they are so small, they go everywhere. From the toxin’s perspective, they compete with the natural red blood cells. Since there are so many of them, they significantly reduce the toxin concentration in the bloodstream.”

Zhang describes the creation of these nanosponges as a two-step process. First, blood cells are collected and the hemoglobin is removed using a process developed by Zhang and his colleagues. Then the remaining cell membrane is wrapped around the polymer core. This, he says, is “a spontaneous process. If you control the conditions—the temperature, pressure and external energy—the membrane will automatically fuse onto the particle’s surface by itself.”

This approach to combating toxins has proved successful in initial studies. Zhang believes the nanosponge represents a major breakthrough that will ultimately streamline the treatment of toxic infections. “There are more than 80 families of different pore-forming toxins,” he says. “So instead of developing 80 different treatments, and having to know which one caused the problem in order for the doctor to perform the appropriate treatment, you can ignore all those things. With the nanosponge, we don’t care where the toxin came from. This opens a completely new approach to toxin treatment.”

NEUROSCIENCE TREATMENT
Neurological diseases and disorders have long posed treatment challenges for health care professionals, but recent advances are promising.
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Progress against one autoimmune disease is progress against them all.
Gamma Knife surgery—which was developed in Sweden and later approved and introduced for use in the United States—is a minimally invasive radiosurgery procedure in which multiple beams of gamma radiation are focused on targeted areas in the body. This pinpointed radiation kills cancer cells and shrinks tumors while leaving surrounding tissue unaffected, and Gamma Knife has proved successful in treating brain tumors as well as neurological disorders such as essential tremor. In Seattle, Swedish Radiosurgery Center introduced Gamma Knife treatments in 2010 to treat brain disorders including cancer and neurological conditions; in the three years since its debut, Dr. Ronald Young and radiosurgery center staff have successfully treated more than 1,000 patients with essential tremor using Gamma Knife, making the center among the most experienced institutions in the world in the use of this technology.

Now, researchers at the Swedish Neuroscience Institute (SNI) are developing ways to add therapeutic ultrasound to the medical tool kit, giving physicians and their patients a greater range of options for treating this challenging class of disorders. Ultrasound has not been around as long as Archimedes’ screw, but diagnostic ultrasound has been around long enough that most of us now take it for granted. Ultrasound images are a familiar aspect of prenatal care, and many of us have seen ultrasound images of our own hearts during cardiac-stress tests. Recent refinements in the technology, however, are prompting health care professionals to take a fresh look at this familiar medical tool.

At SNI, David Newell and his colleagues are making breakthroughs in the emerging field of therapeutic neurosonology, bringing an additional treatment option to patients who suffer from a variety of conditions, including cancer, stroke and essential tremor. Newell, who serves as chief of neuroscience at SNI, says that it is not surprising that so many of these innovations are being developed in Seattle, as the city has long been a hub for innovation in the field of ultrasound.

“There are more companies clustered here that are doing medical ultrasound than anywhere in the world,” he notes. “That comes from the sonar that was developed for use in the submarines that were based here, and the technology from the advanced applied physics lab at the University of Washington. There are a lot of physicists who were working in this area, and they came up with some of the first ultrasound medical applications.”

Therapeutic ultrasound is not an entirely new concept; it is commonly used to break up kidney stones, for example. But that is possible because the sound waves only need to penetrate soft tissue. Getting the sound waves through bony structures such as the human skull to treat tumors or break up blood clots represents a much greater challenge.

It was once assumed that these sound waves could not penetrate the skull at all. But in the

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early 1980s, Rune Aaslid, a Norwegian physiologist, developed a technique called transcranial doppler. This finally gave physicians the ability to measure blood flow from vessels inside the skull. As important a breakthrough as this was, however, it still limited the use of ultrasound to diagnostic and imaging applications.

More recently, InSightec, a medical-device company based in Israel, made a breakthrough that allows doctors to focus ultrasound energy inside the skull so precisely that they can actually use it to perform surgery. “They made these helmets with more than 1,000 different sources of ultrasound,” Newell explains. “When you put ultrasound through the skull, it gets deflected by the bone, but they were able to refocus it after it got through the bone by means of sophisticated electronics. They use the same algorithms that you have in the autofocus on a camera, where you have beams of light that all focus on one plane. They were able to control the electronics to achieve a very sharp point of concentration of all the ultrasound beams to the point where they could heat up tissue significantly,” he says, noting that the temperature of the surrounding tissue largely remains normal.

This is exciting news for patients. Newell notes the effect of focused ultrasound is immediate: When cells heat up to 56 degrees Celsius, as they do when struck by focused beams of ultrasound, they die. If necessary, ultrasound treatment can potentially be repeated right away. The Swedish Neuroscience Institute is one of four centers in the United States now involved in testing focused ultrasound technology in humans; as of this fall, the technology was undergoing clinical testing for FDA approval.

Another way to deliver ultrasound inside the skull is through the use of catheters. This, according to Newell, could have important ramifications for victims of ischemic stroke. “With ischemic stroke, where a blood clot goes up into the artery in the brain, the idea is to get patients in within three hours and
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give them a drug called tPA intravenously,” he says. “The drug mixes with the blood, and goes up and starts to dissolve the clot in the brain.”

This has long been the standard treatment for stroke. It suffers, however, from the fact that tPA dissolves the clot from the outside in. This takes time—sometimes, too much time. But studies have shown that ultrasound, used in conjunction with tPA, can cause clots to break up as much as three times faster than they do with tPA alone.

“The phenomenon is called ‘acoustical streaming,’” explains Newell. “You vibrate the clot a little bit, so it agitates and mixes with the surrounding blood so the tPA can reach the inner portions of the clot a lot easier. It’s almost like what happens when you put an ice cube in water: The solid cube has to melt from the outside in. But if you put a snowball in water, and hit it with ultrasound that breaks it up, then you have more warm water hitting the ice crystals.”

Working with the Bothell, Washington-based EKOS Corporation, Newell and his colleagues developed a microcatheter-based system that was capable of delivering ultrasound to the site of a blood clot in the human brain. In 2010 they announced the results of a clinical study dubbed SLEUTH (Safety of Lysis with Ultrasound in the Treatment of Intracerebral and Intraventricular Hemorrhage). Based on the results of that study, engineers at EKOS have redesigned the catheter, and plans for more tests are in the works.

**Cellular Immunotherapy**

Researchers at the Seattle Children’s Research Institute believe that it is important to develop new cancer treatments that are less invasive than surgery and have fewer side effects than traditional approaches such as radiation and chemotherapy. One of the most promising techniques they’ve found draws a type of white blood cell known as T cells from the patient’s own immune system, and reprograms them to zero in on cancer cells and destroy them—without harming any of the patient’s normal tissues.
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As in Liangfang Zhang’s work with nanosponges, the key to this technique is getting the T cells to recognize unique molecular markers on the surface of the cancer cells’ membranes. Once they lock on these targets, the T cells attach themselves to the cancer cells and drill holes in the cell membrane. Enzymes that are inserted through these holes cause the cancer cells to dissolve within minutes.

“So it’s a very specific and very potent killing mechanism,” says Michael Jensen, director of the institute’s Ben Towne Center for Childhood Cancer Research. “In a sense, the tumor cell never expects what’s coming. It doesn’t have the ability to defend itself against this new immune system. It’s the same mechanism that our body has evolved to deal with viral infections.”

Jensen and his colleagues achieve this transformation by inserting artificial DNA molecules into the patient’s T cells. “We can isolate the immune system T cells from a tube of blood drawn from the arm of a patient,” Jensen explains. “And we have very efficient ways of inserting recombinant DNA molecules into those T cells, where they attach to the chromosomes.”

Thus reprogrammed, the T cells form antigen receptors—Velcro-like molecules—that attach to corresponding molecules on the patient’s cancer cells. “It’s a personalized therapy,” says Jensen. “It’s like rebooting the patient’s own immune system with a new app that goes after the patient’s tumor.”

The team is currently focused on using this technique to treat acute lymphoblastic leukemia (ALL), conducting Phase I clinical trials on patients at Seattle Children’s. The patients in these trials are children and young adults, ages 1 to 26, and all have experienced relapses after undergoing chemotherapy. And doctors have announced that a 23-year-old patient has had a positive response to the experimental treatment.

Jensen notes that the age of the patient and the fact that she had already undergone chemotherapy for ALL are required by FDA guidelines for Phase I trials. But he believes that ultimately this technique
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“The exciting part about it is that it’s a platform technology based on genetic engineering that is potentially amenable to treating all forms of cancer,” he says. “Once we show safety in our Phase I trials, we will move on into Phase II and Phase III trials where we will try to treat patients earlier and earlier. Our goal is to replace chemotherapy and replace radiation and surgery with these targeted immunotherapies.”

Sean MacLeod is president of Stratos, a Seattle-based product development company that specializes in commercializing new medical technologies. He has seen a lot of changes in the health care industry since he joined the firm in 1994, and he believes that the industry is now at a crossroads. The health-care system of the future, he believes, will focus on a “continuum of care,” with increasing attention paid to wellness, disease prevention and long-term outcomes. All the while, there will be increasing pressures to contain and even reduce costs.

“The country has to create more compelling, more cost-effective solutions,” he says. “It’s not going to be one technology—it’s going to be several.” MacLeod says these solutions will likely be much more complex, while raising questions that are very much a part of the health care landscape. “How do we get better outcomes at a lower cost?” he asks. “What does that equation look like?”

As with most complex problems, the challenge of solving this equation will require more than desire and technology—it will require imagination. In their research, Drs. Cohn, Zhang, Newell and Jensen have demonstrated an admirable willingness to take unconventional approaches to treating life-threatening medical conditions. It is creative thinking like this that will help the health care system of the future take shape, and that holds the potential promise of delivering quality care for patients at a manageable price.

Dayton Fandray is a writer in Tucson.