New medical technologies are making chronic-care management more consistent and effective—reducing health-care costs and transforming lives.

Smaller, smarter, healthier
Joe just had a pacemaker implanted to deliver electrical pulses to the right ventricle of his heart, to prevent his heartbeat from stopping and keep him from losing consciousness. His entire pacemaker, about the size of a large vitamin capsule, is slipped directly into place in the heart through a vein. Unlike a traditional pacemaker, there’s no box under the skin and no wires. He goes home a few hours later. Instead of delivering pulses at a preset level every few minutes as the first implanted pacemakers did, Joe’s pacemaker monitors the electrical activity in his heart by the microsecond and delivers pulses only as needed.

“This is a closed-loop system,” says Alan Cheng, vice president for clinical research and therapy development, cardiac rhythm management, at Medtronic, a global medical technology company. Cheng is a clinical electrophysiologist and also an associate professor at The Johns Hopkins University School of Medicine. “The pacemaker has two main jobs: to sense what’s going on in the heart, and to pace the heart if it doesn’t see enough electrical activity. It’s taking inputs on what the intrinsic rhythm is, and if it falls below, the device will start pacing and keep it up until the heart regains its rhythm.”

Joe will still have a follow-up appointment, but his doctor today will have weeks’ worth of data to help answer the critical question, “So, how’s the new pacemaker?” The data collected, from Joe’s pacemaker and thousands of other patients, will help refine the algorithms that monitor the heart and control the pulses.

Such advances in miniaturization and artificial intelligence are enabling the development of ingenious devices to help monitor and treat numerous chronic conditions—not only heart disease, but also diabetes (see sidebar, page 4), Parkinson’s disease, cancer, epilepsy, obesity, chronic pain, and many others.

“When you look at overall disease burden as well as the aging population, many clinical areas need to focus on long-term patient management and close monitoring of patients on an outpatient or home-care basis to maintain health and prevent acute complications,” says Diane Robertson, director of health technology assessment for ECRI Institute, in Plymouth Meeting, Pennsylvania, an independent nonprofit organization that evaluates medical practices and products for safety and effectiveness. “[This type of monitoring] is now possible with implantable as well as external smart devices that measure and record key data, give the users alerts and feedback, and send data to databanks to be accessed by the patients’ clinicians.”
Less variability equals better health

Chronic diseases take a tremendous toll, causing not only physical and psychological suffering, but also financial. The Centers for Disease Control and Prevention estimates that 90 percent of the nation’s $3.3 trillion health-care bill goes to treat chronic diseases, and some studies show that “superusers”—the 5 percent of the population with multiple serious chronic diseases—account for half of health-care spending. The American Diabetes Association estimates that diabetes alone racks up almost $240 billion a year in medical costs. Almost a third of that expense is for hospital care related to crises and complications. Cardiovascular disease costs almost $1 billion a day in direct medical expense and lost productivity, according to the American Heart Association, and the disease is implicated in one out of four deaths.

Keeping patients stable is the key to keeping them healthy, by heading off the crises and complications that can land them in the hospital. The new generation of small, smart medical technology devices can have a major impact—not only on people’s health but on the overall cost of health care—by monitoring a patient’s condition and consistently making continuous adjustments. These advances in medical technology reduce the variability that comes with waiting for humans to notice a problem and respond, says Richard Kuntz, an interventional cardiologist who serves as chief medical and scientific officer at Medtronic.

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Diane Robertson, Director of Health Technology Assessment, ECRI Institute
According to the medical device trade organization Advamed the cost of medical devices, even the most advanced ones, represents only about 6 percent of the nation's total health expenses. Kuntz adds, “We could remove those costs completely and it wouldn’t make a dent” compared with what Centers for Medicare and Medicaid Services cites as the biggest costs of care in the United States: hospital care, physician care, and prescription drugs. Kuntz’s goal is to use smart medical devices to reduce those enormous expenses.

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Automated insulin delivery zeroes in on real-time responsiveness

A diagnosis of Type 1 diabetes used to mean a life sentence of manually monitoring blood sugar and administering insulin, the sugar-regulating hormone that the body's pancreas has stopped making. Sugar that's too high—hyperglycemia—can cause heart disease and blindness, and can damage blood vessels, nerves, and kidneys. Sugar that's too low—hypoglycemia—can cause dizziness, disorientation, unconsciousness, and seizures, and can be fatal if unrecognized. Hypoglycemia sends about 100,000 people to the emergency room every year.

About 1.25 million Americans live with Type 1 diabetes, which until recently required them to measure their blood sugar half a dozen times a day, stabbing a finger each time, and administer insulin to keep it within a normal range. Since the introduction of the first commercial insulin pump in 1983, which dispensed insulin on command through a catheter, many patients have escaped the burden of giving themselves insulin injections, but they still need to monitor their sugars and tell their pumps when to dispense insulin, and how much to use.

Today, more than 150,000 people with Type 1 diabetes are using an insulin pump the size of a deck of cards, along with a glucose sensor connected to the body, to keep their blood sugars stable without having to pay constant attention. After a week or so of training to learn the user's patterns of insulin use, the algorithm that coordinates the pump and the sensor is ready for automatic mode. The sensor sends continuous information to the pump and most of the time can determine the correct amount of background insulin needed. The patient has to OK a dose of insulin only if the sensor recommends an amount that falls outside the patient's usual dose. These small devices from Medtronic, enabled by artificial intelligence, are the closest that technology has come to duplicating the functions of a healthy pancreas.

“Prior to this technology, patients had to assume an average rate of insulin needed for the day, and because life is different every day, it was not fully accurate most of the time,” says Ali Dianaty, vice president of research and development for the diabetes group at Medtronic. “We have automated that background side of it, so they don’t need to constantly be thinking about that.”

Medtronic software collects data from the pump and sensor so users and their physicians can track the numbers and compile reports. User data can also help Medtronic refine its algorithms and make future devices smarter over time.
As more smart devices come on the scene, health-care organizations will be able to modify how they use their personnel and facilities.

He predicts they’ll only get smarter and, if needed, smaller. Medtronic’s device, now implanted in more than 35,000 patients worldwide doesn’t need to shrink any more, Kuntz says, but it will benefit from increased memory, processing power, and battery life.

Those new capabilities will help speed the development of a pacemaker that can sense and coordinate electrical activity in all four chambers of the heart, Cheng says. Currently, Medtronic’s miniature pacemaker can sense only one chamber; expanding those capabilities will expand the list of heart conditions the device can help.

Reaping the benefits of better data
Medtronic is working with providers and insurers to make sure its devices improve health in ways that go well beyond a traditional warranty on the device itself. Because these smart devices generate data continually, clinicians aren’t limited to the episodic picture of a patient’s health that they get from a standard medical record. A clinic that’s accustomed to following up with cardiac patients weekly or monthly may not need to see them in person at all, but clinicians may check in virtually instead, changing care plans or tweaking medications based on verbal reports of how patients are feeling along with data from devices. As more smart devices come on the scene, health-care organizations will be able to modify how they use their personnel and facilities. Medtronic is actively working with providers and insurers to develop recommended “care pathways” to help them capitalize on the efficiencies made possible by medical technologies, while still keeping a close eye on patients.

New applications of artificial intelligence will also keep pushing the frontiers, Kuntz says. Medtronic recently acquired Nutrino, a company that has digitized thousands of photographs of food and linked the photos to each food’s glycemic index (the impact that it has on blood sugar)—a vital calculation that millions of diabetics make at every meal with wildly varying accuracy. “The goal is that you take a picture of the food you’re going to eat, and their algorithm recognizes the food using something that’s like facial recognition,” Kuntz says. It would then compute the total glycemic index and calories for the meal, compare it with

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Laura Mauri, Vice President of Global Clinical Research and Analytics, Medtronic
the 90 percent of patients who are doing fine from the 10 percent who need their treatment plans adjusted. “The final step is to link the sensor information into these new technologies that automatically adjust the treatment,” Mauri says. “We could personalize therapy in real time.”

Everyone wants to be as healthy as possible, and no one wants to go to the hospital. These personalized technologies can head off the crises that routinely jeopardize the lives of chronically ill patients. As devices become more sophisticated, device makers, providers, and payers will find new ways to collaborate to improve care, reduce overall costs, and make better health the norm for the chronically ill.

Pacemakers: A brief history

The devices have come a long way from the bulky boxes of the 1940s that were plugged into the wall for power.

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<td>Wearable external pacemaker</td>
<td>Implantable pacemaker</td>
<td>Rate-responsive pacemaker</td>
<td>MRI-conditional pacemaker</td>
<td>Transcatheter pacemaker</td>
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<tr>
<td>Connected to electrode leads that go through the skin to the heart</td>
<td>Circuitry and power supply are implanted in the body</td>
<td>Has sensors that can increase or decrease the heart rate</td>
<td>Allows patients to undergo magnetic resonance imaging exams within specific conditions</td>
<td>Delivered via a catheter and implanted directly into the heart</td>
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the patient’s history of insulin use, calculate how much insulin will be needed to keep blood sugar stable, and tell the insulin pump to release that amount.

These and other disruptive technologies will enable clinicians to tailor care to each patient’s specific needs, helping to minimize variability in the way patients respond to care, says Laura Mauri, vice president of global clinical research and analytics at Medtronic. In pharmaceuticals, this principle applies to drug regimens based on patients’ genes. “On the device side, it has more to do with how we tailor the treatments according to patterns we see through sensors,” she says. Sensors, whether in the patient’s environment or implanted in the body, can often distinguish...
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Illustrations

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