New medical technology draws on artificial intelligence to combat chronic conditions and radically improve people’s health.

Smarter devices, better patient care
We are at the very beginning of a medical revolution, fueled by our ability to analyze hitherto unheard-of amounts of data using artificial intelligence (AI). AI is enabling the development of smart medical devices that can address some of society’s most persistent and expensive health problems. Conditions such as heart arrhythmias, type 1 diabetes, celiac disease, irritable bowel syndrome, and intestinal cancer can kill or disable millions of people every year and cost billions to diagnose and treat.

Instead of simply dealing with crises, or stabilizing patients with chronic health issues, medical devices can supply data to AI algorithms, which also draw from other data sources to diagnose and predict the course of a disease. The devices can use the resulting analysis to anticipate and prevent crises, detect issues that might have gone unnoticed, and help keep patients healthier.

The development of these smart medical devices is enabled by a combination of miniaturization, more powerful computing, advanced computational modeling, and increasingly sophisticated data analytics techniques for programming AI algorithms.

Much of this development rests on the concept of the “digital twin,” a computer model coupled with real-world data to create digital versions of a physical thing – for example, a machine, or in health care, a patient. Digital twins allow researchers to test many possible designs or treatment strategies virtually.

Digital twins have been used in industries such as aerospace, oil and gas, and manufacturing to improve maintenance and operation of equipment, processes, and systems. In a jet engine, for example, a digital twin uses modeling and simulation to test possible designs before they’re built and predict which ones will perform best, dramatically reducing the expense of developing engine prototypes. Once a prototype is built, designers can use the digital twin to apply AI and statistical analyses to streaming sensor data from the engine to identify and correct possible failures and optimize performance and maintenance.

The technology has transformed ecosystems and business models and is now doing the same for health

Key takeaways

1. Advances in artificial intelligence, miniaturization and wireless connectivity are enabling the development of smart medical devices that tap into enormous stores of data to help improve the health of patients with chronic and expensive health conditions.

2. Fueling medical device development is the concept of the “digital twin,” a computer-modeled replica of a physical thing. In health care, digital twins can be used to model both medical devices and patients to see how certain devices work on people with specific conditions. Once there’s a real-world device and a real-world person, the interaction between the two generates more data, which further refines the device’s performance.

3. Medical devices that can “learn” and adapt their performance to the needs of a specific patient will contribute to more tailored, individualized approaches to patient care.

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care, says Mark Palmer, distinguished scientist at Medtronic, a global medical technology company. “Digital twins are allowing us to optimize health, shift from unplanned emergency events to planned interventions, and extend the quality of life.”

Although biological systems have more variables than mechanical ones, and many are still not well understood, recent advances in computing power and AI are helping researchers create “virtual patients”—computer simulations using real patient data—to see how models of medical devices work on models of people. Narrowing thousands of potential choices to the most promising ones vastly improves the chances that the ultimate design will be successful, Palmer says. “Without these technologies, the development team has limited opportunity to iterate and vary the design because of the time and cost.” It’s also safer and more ethical to perform tests on virtual patients than on real ones.

“People with diabetes are of all shapes and sizes and have all kinds of variations in how their metabolism works, so we need a way to adapt and personalize.”

Ali Dianaty, Vice President for Research and Development, Medtronic

Once a computer model of a device has been validated by real-world experience, Palmer says, the US Food and Drug Administration (FDA) may accept the model as partial evidence of a product’s safety and effectiveness, reducing the size of clinical trials and the burden of enrolling additional real patients. Modeling and simulation have already shortened the approval cycle for some new devices, getting them into the hands of clinicians and patients up to two years earlier.

Here are three examples of how computer modeling and AI are woven into devices to help keep patients healthy.

### How to educate an insulin pump

More than 3,500 patients with type 1 diabetes have contributed a month’s worth of meticulously complete data on their diet, exercise, blood glucose readings,
Combining the patient database with what’s known about how insulin reacts with carbohydrates, researchers can model a wide range of metabolic scenarios to design algorithms that help keep patients’ blood glucose within the recommended range at least 70% of the time as they go about their normal activities (see “Peace of mind through automation,” page 5). Once they narrow down the algorithms that seem promising, researchers can perform mock clinical trials on virtual patients shaped from data in the database.

Patients have to tell even the smartest insulin pump to administer extra insulin when they’re planning to eat; that amount is based on the number of grams of carbohydrates they expect to consume. Often, Dianaty says, they overestimate or underestimate and have to compensate later according to their post-meal glucose levels. One focus of algorithm development is those patterns of compensation: the goal is for the algorithm to better predict how much insulin is the optimal mealtime amount for a given patient.

Image analysis for the small intestine

Gastroenterologists can examine the inside of the stomach or the colon by inserting an endoscope in the appropriate orifice, but the small intestine, which sits between the stomach and the large intestine, was extremely difficult to examine internally until 2001, when the FDA approved capsule endoscopy. A tiny, swallowable device takes thousands of images during its trip through the digestive system. It has become the gold standard for looking at the small intestine, which can hide ulcers, cancer, polyps, and inflammatory bowel disease, among many other conditions that can escape detection by x-ray imaging, the only technique available previously.

“We didn’t know how some diseases were manifested in the small bowel until this technology,” says Dori Peleg, director of AI and technical fellow at Medtronic.

Each capsule endoscopy study produces tens of thousands of images – too many for a gastroenterologist to even begin to review. That’s where AI comes in. “Polyps may appear in only one or two frames,” Peleg says. His team’s work has focused on training algorithms to spot those frames, as well as those that show bleeding and other problems, and pull out suspicious images for human review.
Jennifer McVean is sleeping soundly for the first time in 30 years, thanks to smart automation.

A pediatric endocrinologist at M Health Fairview in Minneapolis, McVean was diagnosed at age 11 with type 1 diabetes, a condition in which the pancreas stops producing insulin, a hormone that controls blood glucose. McVean’s life and health depend on the accuracy of her insulin dosing. Every day, she has to monitor her glucose levels, food, and exercise and make multiple decisions to try to keep her blood glucose levels “in range” (between 70 milligrams per deciliter and 180 mg/dl). Nighttime is particularly anxiety-provoking, as harmful drops in glucose levels can occur during sleep.

McVean calls the new technology “groundbreaking”—especially for her diabetes patients who face the same challenges she did as a child.

“The mental burden of diabetes is immense,” McVean says. “People with diabetes must ask themselves countless questions. ‘Should I increase or decrease my dose? Did I exercise? When should I eat? Do I need to wake myself up overnight?’ I make all those decisions, and it’s exhausting. This technology is life-changing.”

Parents of children with diabetes who are old enough to use an insulin pump (per the approved labeling – 7 years of age and older) can send their kids to school knowing that the pump is always working in the background to maximize the time blood glucose is in range. School nurses and caregivers still interact with the device, adjusting it to compensate for food and exercise, but their task is much simpler because of AI.

McVean looks forward to even smarter pump-glucose monitor systems that track food and exercise so that she and her patients no longer have to painstakingly measure every morsel of food they put into their mouths. The learning ability of AI will someday enable a pump that simply needs to be filled with insulin.

“Every person with diabetes is different, and even in the same person, diabetes is different every day,” says McVean. “AI has the potential to significantly decrease the burden of diabetes, allowing people with diabetes greater freedom and health.”
“All these devices that collect information will become stronger when we establish platforms that collect longitudinal data.”

Laura Mauri, Vice President for Global Clinical Research and Analytics, Medtronic

“This AI never gets tired or is distracted, helping the physician to find the pathologies” and make diagnoses much more quickly, says Giovanni Di Napoli, who leads the business unit responsible for capsule endoscopy at Medtronic.

The more data the algorithm reviews, the more accurate it gets over time. “You can get amazing, even human-level performance in identifying images if you have enough data,” Peleg says.

Capsule endoscopies take several hours, but patients can pursue their usual daily schedules while the capsule makes its journey through the body. The capsules are also approved in certain circumstances for studying the esophagus and large intestine; each requires developing AI specific to that area. The capsules could someday provide a welcome alternative to screening colonoscopy in some patients if the capsules and their AI performance can achieve accuracy comparable to current practices.

Modeling the heart

Cardiac defibrillators have one job—to get the heart back on track in the case of an irregular rhythm. Early versions of the devices did not have built-in intelligence; their objective was to deliver an electrical pulse to interrupt and reset a dangerously fast rhythm. While effective, those jolts could be uncomfortable and distracting for patients.

Modern pacemakers and defibrillators are programmable and can be highly customized to individual patients, but that ability presents new challenges for the devices’ developers, says Darrell Swenson, an engineering manager for Medtronic who works on modeling the electrophysiology of the heart. “There’s a lot more computing power on the devices, and they can make decisions on how they treat a patient,” he says. “There are multiple pathways that a therapy could take, and we need to verify that it’s safe in every pathway.”

Swenson draws an analogy to a self-driving car, which may drive thousands of miles and never encounter a pedestrian but needs to know exactly what to do if one appears. Using detailed data on the electrical impulses from thousands of patients’ hearts, Swenson and his colleagues can create virtual patients and test algorithms for new electronic heart devices in all possible conditions.

Now they’re using AI to address life-threatening ventricular fibrillation, which older defibrillators were programmed to correct with powerful and sometimes painful shocks. “VFib” can’t be studied in a research setting with human subjects, because inducing the condition is difficult to do in a safe and ethical way. But using simulations, Swenson’s team is teaching the latest generation of defibrillators to assess the condition and “nudge” the heart back into rhythm.

The more data, the better

The potential of AI goes beyond improving the performance of individual devices, with opportunities to improve the level of medical care generally, says Laura Mauri, Medtronic vice president for global clinical research and analytics.

“All these devices that collect information will become stronger when we establish platforms that collect longitudinal data,” which will enable the AI to pinpoint the approaches that work best in the long run. For example, that information on outcomes could improve care in patients with chronic conditions or in cancer care, where effectiveness of treatments can vary dramatically depending on specific characteristics of the patients, their conditions, and the treatments they receive. More powerful data can lead to more tailored approaches.

“The fundamental building blocks are there for pulling all these data sources together,” Mauri adds. “The ideal is a learning health-care system.”
Chronic diseases: A snapshot

The broad category of conditions that last one year or more and require ongoing medical attention are known as chronic diseases. Here are a few:

Heart arrhythmias

Arrhythmias are conditions in which the heartbeat is too fast, too slow, or irregular. Here are some common arrhythmias:

- **Atrial fibrillation (AFib):** upper heart chambers contract irregularly
- **Bradycardia:** slow heart rate
- **Conduction disorders:** heart does not beat normally
- **Premature contraction:** early heartbeat
- **Tachycardia:** very fast heart rate
- **Ventricular fibrillation (VFib):** disorganized contraction of the lower chambers of the heart

VFib is considered the most serious cardiac rhythm disturbance and leads to cardiac arrest and death if not immediately corrected.

It is estimated that between 2.7 million and 6.1 million people in the United States have AFib.

Type 1 diabetes

Type 1 diabetes is a chronic condition in which the pancreas produces little or no insulin.

1.6m

Number of people with type 1 diabetes in the US, including 187,000 children and adolescents

Potential complications:
- Cardiovascular disease
- Nerve damage
- Kidney disease
- Eye complications
- Foot problems
- Skin disorders
- Hearing impairment
- Alzheimer's disease
- Depression

$327b

Estimated total economic cost of diagnosed diabetes in 2017, a 26% increase from the previous estimate, in 2012

Source: American Diabetes Association

### DIGESTIVE DISEASES

Up to 70 million people are affected by digestive-tract disorders in the US, according to National Institutes of Health data from the last two decades. Here are stats on the number of people who have, are annually treated for, and die because of specific digestive diseases.

#### Irritable bowel syndrome

Ambulatory care visits:

1.6 million

<table>
<thead>
<tr>
<th>Hospitalizations</th>
<th>280,000</th>
</tr>
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<tbody>
<tr>
<td>Mortality</td>
<td>21 deaths</td>
</tr>
<tr>
<td>Prescriptions</td>
<td>5.9 million</td>
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</tbody>
</table>

An estimated 10% to 15% of US adults suffer from irritable bowel syndrome, yet just 5% to 7% have been diagnosed with the disorder.

Source: American College of Gastroenterology

#### Inflammatory bowel disease

The term describes two conditions characterized by chronic inflammation of the gastrointestinal tract:

- **Crohn's disease**
  - Ambulatory care visits: 1.1 million
  - Hospitalizations: 187,000
  - Mortality: 611 deaths
  - Prescriptions: 1.8 million

- **Ulcerative colitis**
  - Ambulatory care visits: 716,000
  - Hospitalizations: 107,000
  - Mortality: 305 deaths
  - Prescriptions: 2.1 million

In 2015, an estimated 1.3% of US adults reported being diagnosed with inflammatory bowel disease.

Source: Centers for Disease Control and Prevention
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Footnotes


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