

THREE KEYS TO UNLOCKING DATA-DRIVEN HEALTH CARE



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The Power of Data: Driving Progress and Improving Outcomes

Medtronic's history is deeply rooted in the medical device industry, but ultimately, it's our identity as a technology leader that will help us achieve our mission of alleviating pain, restoring health, and extending life for people around the world.

But in an era when people can track everything from steps taken and calories consumed to up-to-the-minute breaking news, a disconnected and inefficient health care system makes it so much harder to achieve success in improving health. The simplicity we see in our everyday gadgets is often missing in the patient's journey, the hospital setting, and everywhere in between. Systems are out of date, and what's more, these inefficiencies force our health care practitioners to take time away from delivering care—costing providers time and money.

These challenges erode the ability to provide value and improve lives. At Medtronic, we believe that to truly enhance care, we must help lead the industry toward the future, which includes a value-based system driven by data and analytics to improve clinical and economic outcomes.

Data and analytics provide valuable insights for patients, providers, and payers alike, and thrust the health care system toward integration. Providers can reduce the variance of

in-hospital care by directly measuring clinical outcomes in relation to their actions. By compiling data and using analytics to create patient risk profiles, we can help providers focus treatment on the patients who need it the most. This leads to better clinical outcomes for patients and more efficient use of health care resources.

Medtronic is working hard to push this integration by driving meaningful innovations that harness the power of data to improve overall care and efficiency. By using implantable remote monitoring systems that send real-time patient data directly to providers, we ensure quicker and more accurate patient diagnosis and treatment. Patients are empowered to practice safer self-care in the comfort of their own homes through programs that provide physicians with the data needed to intervene if risky behaviors emerge after care moves beyond hospital walls.

We're also joining forces with other organizations in order to drive innovative progress using data. Our consulting services focus on helping hundreds of catheterization labs and operating rooms use data and analytics to streamline operations and reduce patient wait times. And by partnering with IBM Watson, we created the first and only device in diabetes care that continuously collects live data and

automatically provides personalized sugar-level adjustments—preventing costly and inconvenient hospital stays.

Of course, challenges remain in our quest to integrate data and analytics with how providers work to make sure the information is accurate and truly actionable. But we will be at the forefront of efforts to work together to harness data in the right way to improve patient health.

Looking forward, we know that continuing to develop partnerships across all aspects of technology and health care will be crucial to successfully building a value-based environment. With progress comes new challenges, such as maintaining patient privacy in a data-driven health care world and using data to predict rather than just diagnose and treat patients' diseases. We will continue to use our expertise to move beyond these new hurdles. But we also know we cannot do it alone. We must push this new frontier in health care further, together.

ABOUT MEDTRONIC

As a global leader in medical technology, services, and solutions, Medtronic improves the lives and health of millions of people each year.

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New types of data analytics are on track to deliver consistent, provable value in health care. Here are three keys to unlocking today's data in order to help health systems dramatically improve patient care and operating efficiencies in treating chronic conditions.

Health care systems around the world are transitioning to new business models in order to improve patient care and operating efficiencies. The pressures on providers to find new models are significant, particularly for patients with chronic diseases—such as diabetes and cardiovascular disease—which now account for 60 percent of deaths globally. The number of people with these conditions is rising at worrying rates. For example, the number of people with diagnosed diabetes in the United States has climbed from about 17 million in 2007 to roughly 24 million now, and the total direct and indirect annual costs of care are estimated at more than \$250 billion.

New drugs, devices, and personalized therapies, along with innovations in delivery systems, all offer new approaches for the treatment of a wide range of chronic conditions. These innovations are underpinned by digital tools and technologies that range from traditional electronic health records (EHRs) to data-based integrated diagnostics platforms to cloud-based patient monitoring systems. Wearable sensing devices, for instance, offer the opportunity to monitor and improve care for patients outside the formal health care delivery environment. Health systems are applying more powerful analytic technologies—including artificial intelligence approaches such as machine-learning algorithms. And researchers are not just unlocking medical data—they are also “re-envisioning” how such data should be collected and applied.

Across health care today, data-driven analytics is a deep foundation for measuring and improving outcomes, minimizing variations in care, and demonstrating its value.

To reach these benefits, health systems should seek to align stakeholders on value, bring predictive and prescriptive analytics to personalized care, and further engage and educate patients in their own care.

Done properly, efforts that integrate evidence-based data and sophisticated predictive analytics can identify patients for targeted interventions and improved health behaviors, and allocate resources more efficiently and effectively. The results will include a more effective health system, lower costs, and, most importantly, improved patient health.

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Solutions must be built on effective data analytics and change management, which in turn **live or die** based on their solid alignment among all stakeholders.

KEY 1

Align Stakeholders on Value

Health care systems around the world struggle to achieve and demonstrate consistent, value-based, and provable services, and this struggle is only intensifying as medical costs soar. Solutions must be built on effective data analytics and change management, which in turn live or die based on their solid alignment among all stakeholders.

Today, those stakeholders include clinicians (and their supporting analytics experts and IT staff), patients, medical technology companies, payers, and other players. All must collaborate in gathering, analyzing, acting on, measuring, standardizing, and optimizing the use of appropriate data. This is the foundation for the improved value-based health care delivery of the future (see “The Strategy That Will Fix Health Care,” *Harvard Business Review* 2013).

One key to the foundation is ensuring that physicians and clinical staff participate fully throughout the processes of establishing standard health care outcome measures, creating and validating data analytics, and establishing and ensuring change management steps.

Following this practice, each year “we bring our clinical leadership together and ask: What are our key measures of safety and quality?” says Tina Esposito, vice president for information and technology innovation at Advocate Health Care in Downers Grove, Illinois. “We go through this rigorous process of identifying those measurements and how we will measure them. Using comparative data, we set very challenging goals. We report out every month on our performance.

Leaders and associates all the way to the front line are held accountable for these measures.”

In projects to broaden evidence-based analytic capabilities and clinical actions, it’s crucial to embed the perspectives of physicians and other caregivers in multidisciplinary teams, especially since these clinicians otherwise may not pay attention to the resulting guidelines. “Our analytics team incorporates clinicians, who help to provide a boots-on-the-ground perspective,” says Esposito. “We can create the best algorithm possible, but if we don’t insert it in the clinical workflow in a way that’s meaningful to a physician, and they’re not looking at it, it doesn’t really matter.”

Additionally, experts point out, doctors and other clinical staff may resist change management efforts unless they have actively participated in creating and validating appropriate outcome measurements for those efforts.

Crucially, all players also must be aligned on cost—physicians won’t agree to a change in clinical workflow that reduces costs unless they are convinced that treatment quality won’t suffer.

To better align stakeholders, medical technology providers and hospital systems need to collaborate to think through the clinical workflow and ensure systems are in place to enable new products and services.

“The rush to digitize often leaves out that step of preparing the clinical workflow to accommodate this new flow of information,” notes Kedar Mate, chief innovation and education officer for the Institute for Healthcare

Improvement (IHI) in Cambridge, Massachusetts. “Unfortunately our workflow systems in health care are so fragile that if you don’t pay attention to that step, it will overwhelm the existing systems, and that will quickly make the technologies irrelevant.” (IHI offers a quality improvement toolkit that can help to assess and improve clinical workflows, with components such as a Failure Modes and Effects Analysis tool.)

Some groups have developed frameworks of strategies tailored specifically to implementing digital health interventions, which helps align stakeholders on goals and procedures. Among them is the IDEAS (Integrate, Design, Assess, and Share) framework, described in a 2016 *Journal of Medical Internet Research* article. The IDEAS architecture covers 10 phases in the development and delivery of pilot digital health projects, starting with empathizing with target users and specifying their target behavior and following through to evaluating efficacy in a clinical trial and sharing the findings. (Other researchers emphasize the growing trend to evaluate efficiency by applying suitable analytics to real-world patient data.)

Startup vendors that are rapidly providing innovative digital health devices and services, however, don’t always appreciate the time, attention, and support required to take all of the steps needed for success.

“Silicon Valley entrepreneurs often don’t want to hear these things, because they’re busy disrupting health care and creating incredible technologies,” comments Brennan Spiegel, director of health services research for Cedars-Sinai Health System in Los Angeles and professor of medicine and public health at the University of California, Los Angeles. “But the fact is that digital health is really hard. Being in the clinical trenches, actually doing this stuff, is very difficult.”

Perhaps unsurprisingly, one of the biggest difficulties is reimbursement.

Payers in every country are under enormous pressures to hold down

costs. Although the path for valuing the potential gains of efficiency and cost-effectiveness with new medical devices and procedures can be far from clear, value-based approaches through bundled payments and risk-sharing to guarantee outcomes often are paving the way.

Outpatient monitoring and management services offer one major way to put value into the system and optimize the performance of medical technologies and pharma. Such services, with proper analytics, will reduce overall costs by cutting unnecessary hospital stays, clinic visits, diagnostic tests, and the use of other resources, says Evan Muse, an assistant professor at the Scripps Translational Science Institute and a cardiologist at the Scripps Clinic in La Jolla, California.

Right now, however, getting paid for many of these evolving remote monitoring practices can be a tough challenge, according to Muse, who says, “What will be the appropriate reimbursement for that knowledge and time and effort?”

“If we can demonstrate that remote monitoring keeps people out of the hospital, away from the doctor, and away from other resource-consuming sites, then we could prove that the model is a cost effective model,” says Spiegel. “But we have a long way to go before that vision is fully realized.”

In addition to clinical trial evidence, predictive analytics applied to real-world clinical data can help key stakeholders identify value opportunities, says Sanjeev Mehta, chief medical information officer at the Joslin Diabetes Center in Boston, Massachusetts. For instance, a 2016 Joslin study built a predictive model to estimate the cost of managing a population of 10,000 patients with diabetes. Such frameworks could help better organize care delivery in a value-oriented manner focused less on maximizing volume and more on increasing prevention and other high-value interventions.

Once clinically effective advances in drugs and devices are approved by the Food and Drug Administration,



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payers develop proprietary cost models to address questions such as what support to offer for new health technologies, such as emerging artificial pancreas devices for people with type 1 diabetes. These models must incorporate evidence as to whether these technologies will improve patient health and avoid greater costs down the road by minimizing events linked to disease progression such as hospitalization and kidney dialysis treatment.

“We cannot tweak out anticipated value for everything in medicine, but if we want to identify high-value interventions, we have to be much more serious about including the cost of care,” says Mehta. “A medical device may have a significant upfront cost, but if its use reduces episodes of life-threatening hypoglycemia or diabetic ketoacidosis, the value to our patients and health care system could be very favorable. One important challenge will be for stakeholders to agree on the time horizon used when defining the value of medical interventions.”

KEY 2

Bring Predictive and Prescriptive Analytics Into Personalized Care

In addressing the enormous human and economic costs of chronic diseases, the best hopes for better care lie in more personalized prevention approaches and care delivered to each patient. The best treatments can vary tremendously between individuals with similar-appearing illnesses. Moreover, most people with chronic illness don't fully observe their recommended behaviors, so doctors seek to increase compliance by tailoring their recommendations to reflect the social, environmental, and behavioral factors impacting each patient.

Truly personalized treatment begins with the creation of a complete longitudinal patient record, and then requires health analytics that moves beyond the descriptive capabilities of the past to predictive analytics and then takes the next step into prescriptive capabilities when possible, as noted in a 2016 article on big data analytics in *Nature Reviews Cardiology*.

Cardiovascular conditions, the leading killers worldwide, have long reflected this personalization trend, and personalized care can build on rich existing data platforms for the conditions. The platforms can draw data from advanced clinical instrumentation applied in acute instances, wearable cardiac monitors that help assess patients with less severe symptoms, and telemonitoring systems for pacemakers, internal cardioverter defibrillators, and implantable rhythm monitoring devices.

Moving beyond these well-established health-saving capabilities, “technology developers are busy giving us more sophisticated tools that can help us understand longitudinally, for example, the ups and downs of blood pressure or weight over time,” Mate says. “These tools allow not just the doctor but also the patient to understand the micro experiments they're making in their lives when they tinker with their diet and their exercise regimens.”

“Many people have a heart attack that no one saw coming,” says Spiegel. “Part of the reason for that is because we deliver care in these tiny punctuated moments within a clinic, where we see people for 15 minutes and make decisions and off they go. People spend 99.9% of their lives far away from the clinic, and that’s where things actually happen.”

Spiegel is leading a clinical study aimed at finding better ways to predict cardiac events, which will measure physical and biological phenomena as well as social and emotional phenomena. More specifically, participants will use an FDA-approved home biomarker kit to collect a drop of blood and send it in for analysis. The study also will gather patient-reported outcomes, including everything from physical function to emotional status. These data sets will be combined with fitness monitoring (heartbeat variability and a variety of other parameters) and cardiac rhythm monitoring, and all the data will be analyzed by machine-learning algorithms. “The hope is that we can find a signal in all that noise that can predict who will have a heart attack,” he says.

That’s one example of work that applies the often barely understood power of machine learning to traditional EHR data. Machine learning, which has dramatically altered the structure of online retailing and other industries, is just beginning to make major inroads into medicine, experts note.

Back in 2009, the U.S. Agency for Healthcare Research and Quality estimated that almost half of the potentially preventable hospitalizations in the country were due to heart disease and diabetes, with an annual cost approaching \$14 billion. In the years since, health systems have made solid progress in lowering preventable hospitalization and emergency room visits for many chronic conditions. But the costs remain huge, and rates of preventable interventions have climbed for some populations—for instance, by a fifth in recent years for people with short-term diabetes complications.

In one project aimed at tackling such problems, researchers at Boston University and Boston-area hospitals applied machine-learning algorithms to standard EHR and billing data to predict hospitalizations for heart disease and diabetes about a year in advance. In 2016, the project reported an accuracy rate of up to 82% on that goal.

Cognitive technologies also are being employed in China, where 300 million patients suffer from chronic conditions. “We do not have enough health care providers to take care of those patients, and the medical expense keeps rising,” says Xiaowei Shen, director of IBM Research China.

His group has partnered with Beijing hospitals to exploit EHR databases to find ways to improve care for cardiovascular disease and diabetes. Applying big-data analytics, the researchers have developed new models to predict stroke risk for patients with atrial fibrillation and mortality risk for those who have suffered a heart attack. The technologies also will aid in personalizing treatments and boosting patient engagement through “chatbot” virtual assistants, he says.

Joslin recently announced a partnership with Cyft to incorporate machine-learning techniques into its diabetes care model. The project will integrate novel insights to improve clinical outcomes as well as operational efficiency—demonstrating the value of predictive analytics in transforming health care delivery. From identifying those patients more likely to discontinue use of diabetes technologies to identifying high-risk patients likely to miss clinical visits,

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these insights will support more proactive patient engagement.

Here, the system might go far beyond traditional reporting and analytics to examine thousands of variables, ranging from complex medical and socioeconomic interactions to local weather and traffic patterns—“basically any data we can include will be analyzed without bias to its perceived importance,” says Mehta. He acknowledges the need for data not collected in traditional EHR systems, including patient-reported outcomes, which could further enhance these predictive algorithms.

Capitalizing on these opportunities will require health systems to draw on expertise, external or internal as needed, on machine learning, and on other rapidly advancing artificial intelligence technologies. The payback will be far more powerful individualized understanding of conditions and potential treatments.

KEY 3

Further Engage and Educate Patients in Their Own Care

When patients participate more actively in managing their chronic conditions, they enjoy better outcomes. A study reported in the *Journal of General Internal Medicine* in 2012, for instance, found that patients who were more engaged in their own care were significantly more likely to have good clinical indicators and to receive preventive care, and less likely to smoke, be obese, or be hospitalized.

Health systems constantly seek to improve outcomes by engaging patients more directly in their own care, and clinicians can draw on

findings from social sciences to help encourage healthy behaviors. (Selected current approaches are described in a 2016 Athena Health white paper overview, a 2016 *Annals of Family Medicine* article on patient behavior changes, and a 2016 *QJM* article on exploiting behavioral economics.)

Unfortunately, most people with chronic conditions still don't fully follow what their doctors advise for diet, exercise, and other behaviors. Many studies have shown the difficulty in truly changing behaviors for extended periods of time, although the need to do so is only intensifying as these diseases rapidly increase worldwide.

In cardiovascular disease prevention, “diet and exercise trump almost every medication and test that we can put out there,” comments Scripps's Muse. “It's my job as a physician-teacher to put things in patients' hands. I say, I'm the copilot here, I'll come up with a flight plan and help us understand what is important for us to look at, and then put the power in your hands.”

“Moving the patient out of the role of simply recipient and into the role of a coproducer of health outcome is actually very important,” says IHI's Mate. “That role change is pretty fundamental and one that some patients and clinicians are not prepared for.”

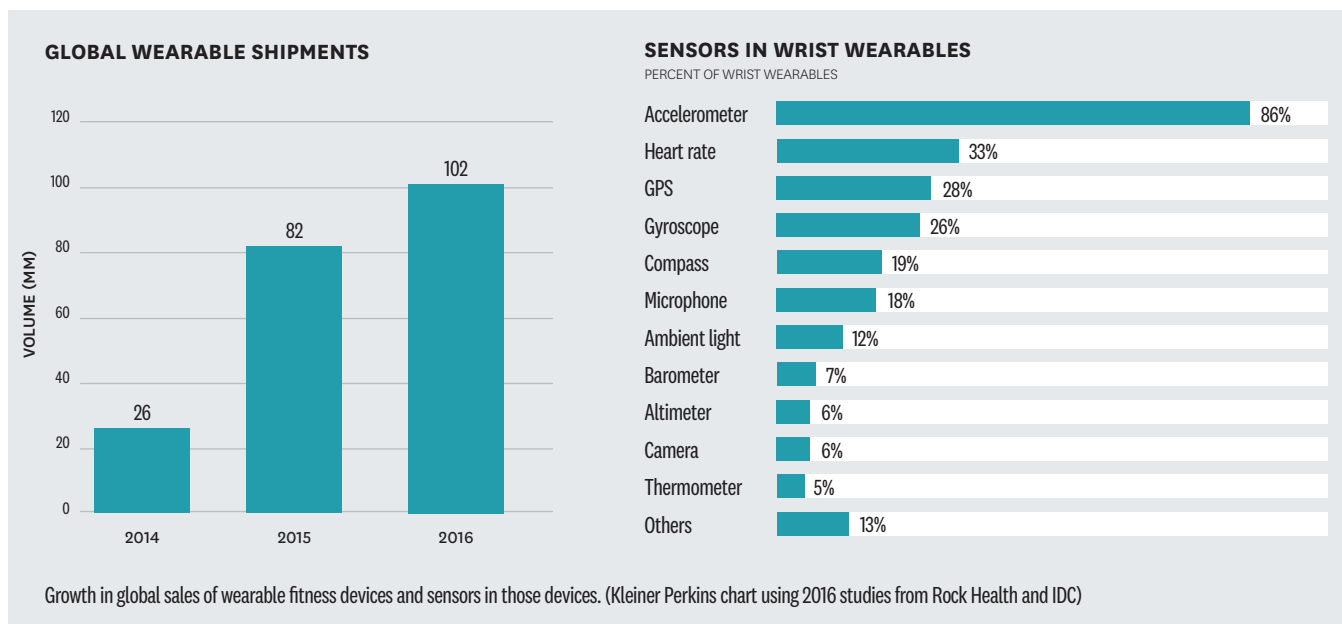
The gap among unprepared patients becomes ever more visible with the rapid spread of self-monitoring devices aimed to help with chronic conditions. For example, a recent study by Berg Insight projects that the global total of connected home health monitoring devices will climb from about 7 million in 2016 to more than 50 million in 2021.

Seeking to close the gap, researchers are testing new digital health technologies designed not only to encourage but to also actively measure patient engagement. In one pilot clinical trial reported in 2017, for instance, patients with uncontrolled hypertension and type 2 diabetes volunteered to take “digital medicine” pills that combined medication with the ability to alert a wearable sensor.

FIGURE 1

WEARABLES = CONSUMER HEALTH + WELLNESS DATA CAPTURE RISING RAPIDLY

Wearables are gaining adoption. Approximately 25% of Americans own a wearable, +12% Y/Y, 2016.



SOURCE: ROCK HEALTH 2016 CONSUMER SURVEY (12/16), IDC, COLLECTION AND PROCESSING OF DATA FROM WRIST WEARABLE DEVICES IN HETEROGENEOUS AND MULTIPLE-USER SCENARIOS (9/16)

*BASED ON ANALYSIS OF 140 DIFFERENT WRIST WEARABLE DEVICES

This sensor also measured physical activities and reported all data to a mobile phone app. The app reminded patients to take their medication and allowed them to visualize their data. Their health care providers could also examine the data and offer guidance. The study found that participants significantly lowered their blood pressure, cholesterol, and blood-glucose levels.

Other digital health clinical trials that have studied more general-purpose wearable fitness devices, which have seen rapid adoption in the U.S. and some other countries, have amply demonstrated the need to strengthen patient engagement. **FIGURE 1** A number of such trials designed to leverage the easy-to-use fitness devices, even those among tech- and health-savvy populations that seem most ready to engage, underline this concern, as noted in a 2015 commentary in *Academic Emergency Medicine*.

More recently, in a study of the MyHeartCounts mobile health application among almost 49,000 consenting early-adopter participants, reported in 2016, fewer than three percent of participants ended up providing all the information needed to assess their 10-year heart risks.

And in another example published in 2016, Cedars-Sinai invited almost 80,000 registrants on its patient portal to report their personal fitness data, but fewer than one percent shared their data.

What was missing from this offering? “There needs to be context, and it’s different if a doctor prescribes it and explains exactly how he or she will use the data,” Spiegel says. “Until patients understand why and exactly how their data is being used, and the benefit to them, they won’t necessarily share data just because they can.”

Overall, **health systems should seek** to align with stakeholders on value, bring predictive and prescriptive analytics to personalized care, and **further engage and educate patients** in their own care.

Moreover, it's crucial to avoid over-promoting the benefits. Although the Cedars-Sinai patients could discuss their uploaded fitness data during visits with their doctors, "we certainly couldn't promise that they would have a more meaningful discussion, because there's no evidence that that's true," Spiegel says.

Maximizing actual patient benefits will require individualized assessments, education, and delivery, often with a sharp focus on those who either are most willing to change their behaviors or need desperately to do so.

"We need to meet people where they are, particularly along their readiness for change," Spiegel says. "Some are ready to eat better, or adhere to their medicine, or follow their doctor's advice, and some are not, and that's an important distinction."

"The solution is not just personalized analytics," agrees Muse. "The successes will start coming when we can do a better assessment of how each patient can change."

One crucial ingredient for change is patient education, which can be personalized not just with advanced interactive learning materials but also with rapidly evolving diagnostic tools, such as handheld ultrasound devices. When his patients with high blood pressure insist they still feel fine, for example, Muse can show them an ultrasound image of the early signs of damage now being inflicted on a given region of their heart, which fully gets their attention and helps motivate them to change some of their behaviors.

From Analytics to Action

Overall, health systems should seek to align with stakeholders on value, bring predictive and prescriptive analytics to personalized care, and further engage and educate patients in their own care.

Health care data is becoming broad and deep enough that predictive analytics can meaningfully inform fundamental questions such as who will best adhere and respond to a given therapy in more real-world settings, says Mehta. That promise needs to be confirmed in clinical studies, he cautions. "But it's a really exciting way for us to start thinking about medicine—proactively intervening to support our patients in a way we haven't done before," he says.

Clinicians must actively integrate such insights into better treatment approaches, whose efficacy and costs can be carefully measured and optimized over time, experts agree.

"Digital health is not a computer science or an engineering science—it's a social and behavioral science," says Spiegel. We have to create hyper-personalized, contextually appropriate experiences for each individual patient. That's what human doctors do every day of the week."



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