That sounds tough. This is a fairly common side effect of Enalapril. Enalapril lowers your blood pressure, which helps prevent strokes, heart attacks and kidney problems. It's a key part of your health so we want to help you manage the side effects.

#### Companion

Would you like to message your doctor about this or visit the CHF support group to see how others have mitigated this side effect?

Message my doctor please.

We're sending this info to your provider so they can help you adjust your care.

#### **Digital Business**

# Successfully Managing Chronic Health Conditions with Human-Centered Digital Therapeutics

By adopting evidence-based digital therapeutics, healthcare organizations can alleviate the mounting costs of caring for the growing number of patients with chronic conditions – and enter the fourth wave of digital healthcare.

### **Executive Summary**

Caring for individuals who suffer from chronic health conditions, such as diabetes, high blood pressure, congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD), costs the U.S. healthcare system billions of dollars annually. Much of this expense is due to ineffective management of these conditions not only by patients themselves but also by the healthcare system. While the U.S. healthcare system generally excels when delivering emergency and acute care, it falters when treating incurable conditions that must be managed and controlled. Payers, providers and industry regulators are all too familiar with the results of ineffective management of chronic conditions: expensive emergency department (ED) visits, hospital admissions and, often, return ED visits and readmissions. Yet despite the costs and care, most



patients experience minimal progress in managing their underlying conditions.

Why does the healthcare system struggle to effectively manage these conditions? In large part, it's because people must change their behaviors: taking medications, eating more healthfully, exercising regularly, practicing self-care — actions that even the healthiest of people find challenging. Rather than giving orders and expecting linear results, health systems, physicians and caregivers must instead support patients throughout their journeys as they experiment with how best to manage their conditions. And payers and regulators must adopt a new and very different reimbursement model that rewards providers based on their ability to successfully manage chronic conditions.

Digital tools, especially rigorous digital therapeutics, can help the industry achieve these goals. Our landmark study "Helping People Heal" revealed that when patients get "warm," supportive care, they're more likely to successfully change their behavior and adhere to prescribed therapies. In our follow-up ethnographic study, we set the goal of identifying the digital capabilities that healthcare organizations can adopt to provide patients with warm care so that together, they can better manage chronic conditions.

In this new ethnographic study, we immersed ourselves in the lives of patients and interviewed physicians at some of the largest U.S. healthcare systems. The study offered clear insights into the capabilities that patients and physicians want when it comes to managing chronic conditions. Armed with these findings, we developed a prototype of a conversational Al-based digital therapeutic solution designed to assist patients with CHF.

This report outlines what we learned about the willingness of patients and physicians to use digital therapies to manage chronic conditions such as CHF, and what the industry must do to incorporate digital therapeutics into its ecosystem, from the care continuum to reimbursement and regulation.



# Understanding the chronically ill patient

More than 100 million people in the U.S. suffer from one or more chronic healthcare conditions.<sup>1</sup> These often-incurable conditions must be managed carefully for patients to avoid disease progression and maintain a good quality of life. But despite the U.S. healthcare system spending approximately \$3 trillion on chronic conditions annually,<sup>2</sup> chronic conditions persist. And despite the industry's focus on patient engagement, efforts to reduce the progression and complications of chronic illness, especially those that are lifestyle-influenced, seem largely ineffectual.

Our initial study on healing revealed that patients require empathic support to help manage the physical and emotional aspects of healing, and yet the healthcare system rarely addresses these needs. Instead, the system tends to be cold and linear, and focused on strict adherence. Most technological solutions mirror these tendencies; that is, healthcare organizations use technology to streamline existing processes rather than reimagine processes from the patient perspective.

This approach has not netted the hoped-for outcomes in managing chronic illnesses. We set out to learn more about the qualities that would make a digital disease management tool effective for patients and physicians.

To gain deep perspective, we started with an ethnographic study of patients diagnosed with CHF and their providers. Selected patients spanned various socioeconomic groups. Our researchers shadowed these individuals and talked with them at length to understand their journeys and the friction points they experience. Our discussions included the following questions:

- What are the biggest barriers you've faced in your daily activities since your diagnosis?
- What were the major pain points during your hospitalization or recent doctor's visit?
- What do you think of digital advances in medicine?
- I How ready are you to manage your medical condition yourself?
- What does the ideal solution look like?
- How would you like technology to support your care?

After weeks of study, we developed a patient persona, Marge. Marge is a 68-year-old woman who lives by herself and is active within her community. She has a history of diabetes and hypertension and is on several medications. Complications from the diabetes and hypertension lead to an emergency department visit, hospital admission and diagnosis of CHF (see QuickTake, page 5). Despite good care at the hospital and detailed discharge instructions, within the month, Marge is readmitted to the hospital. Marge's journey highlights the core patient issues that must be immediately addressed through a reimagined care model:

Lack of clear down-to-earth information about the patient's condition. Patients rarely understand the mechanics of their conditions, how several chronic conditions and treatments might interact, and what their prescriptions are focused on accomplishing.

- I Weak support system. Because of stringent privacy regulations surrounding personal health data, providers can't easily connect patients with other individuals managing similar conditions who could provide practical advice and support.
- Complicated prescription schedule. Individuals with CHF are commonly prescribed up to seven medications and take more than 10 doses a day,<sup>3</sup> which makes it easy to forget a dosage. When taking several medications at a time, it might be hard to pinpoint which one caused an uncomfortable side effect, resulting in patients choosing to skip dosages altogether, especially if no one has clearly explained what the pills do.
- I Lack of adequate post-discharge provider communication. Patients can easily miss postdischarge phone calls from a healthcare system,

or calls might come when the patient feels fine. It's in the moments when the patient "doesn't feel right" – which the provider can't predict – when they most need contact.

- I Limited support for changing behaviors. Adopting new long-term behaviors, such as eating healthier foods, exercising regularly or overcoming an addiction, is a challenge for even the healthiest people. Regular encouragement for weeks or months is required to make new behaviors stick.<sup>4</sup>
- I Inability to effectively self-monitor condition. It's difficult for an individual to distinguish between minor symptoms and more serious ones. Given the difficulty with reaching a primary care physician quickly, frightened patients tend to go to emergency departments.

#### Patients described the capabilities they'd like to see for solving the problems above:

- A simple-to-use, single solution that addresses all their conditions and gives them bite-sized instructions to adhere to their complicated daily treatment routines.
- Clear information about their disease and explanations about what their medications should accomplish.
- I The ability to blend medical adherence and other changes into their existing lifestyles to avoid the disease or illness becoming the focus of their lives.
- I The ability to quickly reach a provider when necessary.
- I Timely guidance, reassurance and feedback from providers about how well they're managing their conditions.

# Quick Take

# Marge: the journey of the chronically ill patient

We conducted an in-depth study of chronically ill patients to understand the factors preventing them from managing their conditions more effectively. Most chronically ill patients suffer from more than one chronic condition, and conditions can exacerbate one another. A person diagnosed with CHF likely has additional diagnoses of hypertension and diabetes and, on average, takes seven prescription medications.

As we talked with and followed patients in their daily routines, a clear persona of the chronically ill patient emerged. She is Marge, a 68-year-old woman who lives alone. Her journey is all too typical in the U.S. healthcare system.



### Marge's journey

- I One day, Marge feels very short of breath. She calls 911; emergency responders take her to the emergency department, where Marge receives acute medical intervention. Her condition stabilizes, and she's admitted to the hospital with the diagnosis of CHF.
- I After a few days, the hospital discharges Marge, sending her home with numerous prescriptions to fill and pages of information about limiting salt intake and increasing her exercise levels. At first, she's happy to be home. But it's now that her real challenges begin.
- I Marge isn't immediately able to fill several of her prescriptions: Her co-pay is unaffordable for one of the medications, and the pharmacy must order the other, making a return trip necessary. She finds it confusing to remember which of her eight medicines to take when, and with what foods – or no food. She inadvertently skips dosages.
- I Marge doesn't know the sodium levels of many of the prepared convenience foods she normally eats. While she puts her salt shaker away, she doesn't make substantial changes in her diet.
- I A difficult week passes, and Marge doesn't feel any better. She doesn't have the energy to go for a short walk. She eats foods that comfort her, including salty chips; does not pick up her additional prescriptions; and regularly forgets to take the meds scheduled outside of her meal times.
- I Marge has no monitoring equipment at home, so she doesn't know what "normal" now is for her. She tries reaching her primary care physician but misses the returned calls from his office. When her breath again gets short, she panics and calls 911. She's taken back to the ED. The hospital re-admits her with acute decompensated heart failure, 22 days after the initial discharge. The provider incurs a financial penalty, and Marge is miserable. There's every indication that this cycle will repeat itself unless Marge receives meaningful intervention and engagement.

Providers want strong patient relationships yet are wary of adding more record-keeping tasks and new steps to their workflow.

## The patient's journey from a provider's perspective

As part of our ethnographic study, we also interviewed healthcare executives, physicians, nurses and social workers at major U.S. healthcare systems to understand their perspective on how to improve the management of chronic conditions. We asked:

- What do you think are the core issues in healthcare today?
- What steps have you taken to solve these issues?
- What do you like and dislike about those steps?
- What is your roadmap to the future?

Key issues that emerged included:

- Lack of visibility into the patient journey. Providers said their inability to track patient behaviors outside the hospital and between appointments results in major gaps in care.
- I Inability to provide the depth of support required by chronically ill patients. Empathy and patient-centric care are essential to helping patients manage conditions, but providers lack the time and resources to provide 24x7 support.

- I Too much of the wrong information. Providers fretted about being overwhelmed with data. As one respondent said, "Physicians get too much data, not actionable information, and this is not sustainable." Providers want to receive only smart, actionable alerts from remote patientmonitoring solutions so they deliver the right help when it's urgently needed.
- Overwhelming workflows. Providers want strong patient relationships yet are wary of adding more record-keeping tasks and new steps to their workflow. Any new data exchanges must be smoothly integrated into existing processes and systems.

The ethnographic findings indicated that an effective chronic-condition management solution, complemented by clinical treatment, would need to knit together patients and providers, provide a support system and offer near-constant, highly personalized information and patient feedback. These requirements validated the need for a digital therapeutics-based approach to address chronic conditions.

# Applying digital therapeutics to chronic conditions

Digital therapeutics is a relatively new discipline of evidence-based, clinically safe, physicianprescribed disease management solutions delivered via digital channels to enhance or replace traditional treatments.

These therapeutics differ vastly from the more than 300,000 health apps available to consumers, as they combine connected health, telemedicine,

Internet of Things (IoT) devices and disease management algorithms to create evidence-based solutions. They must meet clinical safety standards and integrate smoothly into provider workflows, including reimbursement cycles. The most effective digital therapeutics are designed around the needs of the humans involved in the treatment, not the processes of the organization. Digital therapeutics represent the fourth wave of digital healthcare (Figure 1). The first wave centered on remote patient monitoring, which involves providers tracking patient vital signs and intervening proactively while teaching patients to manage their disease. However, this model hasn't delivered on its expected value. Chronically ill patients are not motivated by metrics,<sup>5</sup> and can lose interest if tools fail to keep them engaged<sup>6</sup> or are perceived as inaccurate and/or difficult to use.<sup>7</sup>

The second wave of digital healthcare – virtual care and telemedicine – attempted to solve these issues by adding a human touch: encouragement from nurses and providers. This model is difficult to scale and sustain, however, given that 60% of Americans have at least one chronic condition,<sup>8</sup> requiring continued support for months or years.

Smartphones ushered in the app revolution and the third wave of digital health. Individuals today can choose from hundreds of thousands of healthrelated apps. However, fewer than 1% of these apps are subject to randomized control trials to demonstrate efficacy.<sup>9</sup> Further, only 36 apps account for nearly half of all downloads, and 40% have fewer than 5,000 downloads.<sup>10</sup> Such apps aren't likely to easily integrate into clinical workflows.

scalable to large patient populations.



#### Evolution of digital technology in healthcare

Digital therapeutics solutions build on the strengths of earlier waves of digital technology and address their shortcomings. They collect data and discern meaning from it. These therapeutics are always available, scalable and adaptable to patient moods and progress. And they connect patients to providers and support groups as easily as an app and are backed by research and clinical trials with proof of efficacy. Digital therapies augment clinical therapies, from prescription medications to new diets and exercise regiments. They address the fact that an individual's ability to effectively manage a chronic condition is tightly linked to behaviors shaped and influenced by social, cultural and environmental factors (see Figure 2).<sup>11</sup>

#### Influences on patient behavior

Many different factors influence patient behavior. Healthcare organizations can address these using digital therapeutics built with Al and machine learning capabilities that enable them to adapt to a specific patient's key influences.



Helping people change their daily habits typically requires extensive one-on-one counseling with trained professionals<sup>12</sup> and a great deal of personalized support that the U.S. healthcare system cannot afford. We set out to explore new digital therapeutics that would make these interventions less expensive, more effective and significantly easier to scale. Using the survey findings, we prototyped a digital therapeutics solution specifically for patients suffering from CHF, an extremely complicated illness that costs the U.S. \$30 billion annually.<sup>13</sup> Virtually all CHF patients have one or more chronic illnesses, as CHF often results from poor management of other chronic conditions, such as diabetes or hypertension. Because patients wanted a single tool to manage all conditions, rather than several specialized apps, CHF was the optimal test candidate for our prototype.

# Al-driven care companion generates authentic warmth and connections

Our digital therapeutics solution prototype explored how a conversational AI-enabled "patient companion" could assist a CHF patient. The comprehensive illness management solution starts at the point the patient is discharged from the hospital, to assist with transition of care. It enables remote patient monitoring through symptom tracking as recommended by American Heart Association guidelines, as well as vitals tracking through automatic synchronization with IoT devices to enable timely and proactive intervention.

To design empathy into the therapy, we trained the Al-based system to recognize and respond to different moods and leveraged proven behaviorchange models and techniques to nudge patients through various stages of the behavior-change journey. The solution also offers patients multiple secured channels of connection to providers, friends and family, as well as a vetted support community. To validate the prototype's alignment with patient needs, we tested it with previously hospitalized CHF patients.

Patients held wide-ranging conversations with the AI agent in the prototype. They discussed post-diagnosis aspects of their lives, including vitals monitoring, medication adherence, provider communications, behavior and lifestyle changes, dietary habits, emotional wellness and peer support. They even ventured into topics such as dealing with anxiety and how to find a new life purpose.

Interacting with the AI agent, patients experienced context-driven, personalized conversations and received the on-demand education, motivation and support missing in their healing journey. As one patient said, "With any disease, if you don't have support and love, you're done." Patients reported that these features encouraged them to commit to new behaviors and achieve better outcomes.



# Digital therapeutics take root in the healthcare ecosystem

Helping chronically ill patients adopt healthier behaviors is only one aspect of digital therapeutics success. For these new therapies to thrive, they need to be tightly woven into the industry's clinical, reimbursement and regulatory tapestry (Figure 3).

Only then will digital therapeutics become utilities that the industry can draw on to achieve its triple aim of better access, improved patient outcomes and reduced cost of care. Digital therapeutics are beginning to achieve this status, as the following indicators reveal:

# Digital therapeutics in the healthcare ecosystem

Digital therapeutics must be embedded in healthcare's regulatory and reimbursement structures for providers, payers and patients to adopt them.



Figure 3

- н Provider reimbursement approval. An encouraging move to promote digital therapeutics came when The Centers for Medicare & Medicaid Services (CMS) finalized a ruling in 2018 defining the use of remote patient monitoring devices as part of a CPT code, 99091. This code can be billed for each 30-minute segment spent interpreting remote patient monitoring data, one time per patient per month, at a reimbursement rate of \$59. Further, the charge may be billed in conjunction with chronic care management, transitional care management and behavioral health integration codes already used by providers for the CHF population.<sup>14</sup> Many providers may find that the CMS reimbursement rate, plus costs saved by preventing readmissions and emergency visits, will cover their digital therapeutics investments.
- Regulatory approval. Providers said they want clinical safety assured before they prescribe digital therapeutics. As a positive development, the U.S. Food and Drug Administration (FDA) is testing a digital-health software precertification program with nine companies, including Apple, Alphabet's Verily and Pear Therapeutics.<sup>15</sup> If precertified, a software-as-a-medical-device (SaMD) provider might be able to fast-track premarket review or avoid the process altogether for lower-risk solutions. This precertification pilot creates an opportunity to speed the release of digital therapeutics.

# The digital value proposition

With CMS and the FDA signaling acceptance of digital therapeutics, we expect to see new competitors enter the market. A wide variety of healthcare organizations will benefit from these tools, including:

- Risk-sharing programs. Reimbursements for accountable care organizations (ACOs) and population health management programs depend on the ability to meet the Healthcare Effectiveness Data and Information Set (HEDIS) measures established by the National Committee for Quality Assurance (NCQA). Digital therapeutics designed to increase care access, improve health outcomes and reduce costs tightly align with HEDIS goals. Further, well-designed therapeutics should enable risk-sharing organizations to achieve these metrics with lower operating costs and, thus, increased ROI.
- Health systems. Under the Hospital Readmission Reductions Program (HRRP), CMS reduces reimbursement when a hospital crosses its threshold for 30-day readmissions. CMS tracks CHF patient readmissions, and if more than 20% of patients are readmitted less than 30 days after their initial discharge, hospitals incur financial loss. Digital therapeutics designed to help patients manage complex conditions and that enable early, effective interventions in lower cost settings of care will help providers reduce costs while helping patients adhere to their discharge plan, overcome barriers, enjoy better heath and achieve a higher quality of life.

- Federally qualified health centers (FQHC). Neighborhood ambulatory care clinics tend to have strong relationships with local chronically ill patients. Digital therapeutics can help these providers achieve better outcomes and avoid the higher rates of ED visits, in-patient admissions and readmissions that can adversely affect reimbursement rates. Digital therapeutics tools can also help FQHCs meet several of the wellness quality metrics that require a direct patient-intervention channel.
- I Insurance companies. Digital therapeutics can address adverse behaviors that lead chronically ill patients to costly ED visits and hospital stays. Our research indicates patients using a digital therapeutics solution are more likely to fill prescriptions at the outset, engage more effectively in their care, and understand and manage symptoms. These actions help decrease 911 calls, hospital admissions and 30- and 90day readmission rates, as patients change diets and habits. Better health means more satisfied patients and lower cost of care.

In putting digital therapeutics into practice, healthcare organizations might first introduce a digital therapy to their most seriously ill patients, such as those with CHF. They might then expand the program to patients predicted to develop CHF within a year, and then to patients diagnosed with other chronic illnesses, such as diabetes or COPD, conditions that are often a precursor to CHF if not well managed. Following this timeline, risk-sharing organizations and providers can receive a fast return on helping the highest-risk patients while planning to keep other patients' chronic diseases from progressing.

### **Digital therapeutics: getting started**

Our anthropological observation and patient study validated the design fundamentals for effective digital therapeutics. Therapies must be contextual, adaptable, personalized and warm while also incorporating proven treatment algorithms and solid analytics and alert technologies. Digital therapeutics must also align with a healthcare organization's overall strategy so they can drive clear clinical and business objectives. A checklist like the one in Figure 4 can help organizations scope requirements for digital therapeutics and evaluate offerings accordingly.

#### **Checklist for digital therapeutics initiatives**

Goals	Current Pain Points	Required Features
<ul> <li>Reduce 30-day readmission rates</li> <li>Achieve quality metrics</li> <li>Improve patient engagement</li> <li>Reduce in-patient care</li> <li>Improve effectiveness of office visits</li> <li>Increase patient satisfaction</li> <li>Improve outcomes</li> <li>Reduce overall cost of care</li> <li>Other</li></ul>	<ul> <li>Providing proactive patient intervention</li> <li>Ensuring adherence with medication and discharge plan</li> <li>Keeping up with documentation and data churning</li> <li>Providing patient education and affecting behavior change</li> <li>Establishing routine follow-up visits</li> <li>Obtaining referrals</li> <li>Reaching patients at home</li> <li>Gaining insight into patient treatment plan adherence and challenges</li> <li>Patient barriers and social determinants of health challenges</li> <li>Other</li> </ul>	<ul> <li>EMR integration</li> <li>Patient feedback and communication mechanism</li> <li>Smart vitals monitoring</li> <li>Evidence-based solution</li> <li>Clinical personnel check-in</li> <li>Support for comorbidities</li> <li>Configurable features per patient</li> <li>Other</li></ul>
Optional Features	Payment Model	Current Solutions
<ul> <li>Preventive and lifestyle coaching</li> <li>In-app video and audio conferencing features</li> <li>Integration with other home assistance devices</li> <li>Multiple language support</li> <li>Integration with pharmacy to track prescription status</li> <li>Multiple treatment plan support</li> </ul>	<ul> <li>Patient health plans</li> <li>Quality department budget</li> <li>Population health management plan</li> </ul>	<ul> <li>Never piloted digital medicine</li> <li>Satisfied with current solution</li> <li>Current solution doesn't close gaps in care and communication</li> </ul>



The medical community accepts that patient engagement is the key to good health outcomes. Our ethnographic studies of patients have shown that when engagement is limited to appointment scheduling, follow-up visit reminders, medication refills, etc., it can't effectively help individuals managing chronic illnesses. Digital therapeutics built on a behavioral science foundation and validated through clinical study can result in true engagement and real behavior change that leads to improved health outcomes at reduced cost.

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