STANFORD BYERS CENTER FOR BIODESIGN

CASE: BIOE273-5
DATE: 07/122022

ESTABLISHING LONG-TERM BUSINESS VIABILITY: OMADA HEALTH

"If you can help somebody with prediabetes not go on to get type 2 diabetes at about the same rate as the original DPP, it actually saves the health system money... It is very tough to convincingly show ROI in areas of prevention, but because diabetes costs are so high, helping people with prediabetes makes sense." [1]

– Sean Duffy CEO, Omada Health

Omada Health is a digital behavior change pioneer that provides an economical, evidenced-based prevention program to people at risk of developing type 2 diabetes. Modeled after an effective intervention tested in a major NIH study, Omada's offering combines hardware, software, professional coaching, and social support to deliver significant weight loss and diabetes risk reduction over sustained periods of time.[2] When developing the concept, the Omada founders were convinced that their technology could play a meaningful role in decreasing the burden of chronic disease. Their challenge was figuring out how to build a sustainable business around the intervention to ensure that it would reach the scores of people who would benefit from it most.

Background

The company now known as Omada Health was conceived as an internal project at global design and innovation company IDEO, with the goal of using design thinking and digital technology to help prevent chronic disease. The need was compelling; chronic diseases such as heart disease, stroke, and type 2 diabetes are the most common and costly of all health problems. They are also among the most preventable due to their linkage to modifiable risk factors such as poor diet, lack of physical activity, tobacco use, and alcohol consumption.[3] Adrian James, head of IDEO's medical projects division, signed up for the project, along with health and wellness specialist Sean Duffy.

To determine a specific focus for their endeavor, Duffy and James researched the precursors to chronic conditions, looking for ways to intervene that would satisfy IDEO's three lenses of human-centered design: desirability in satisfying a human need, technical feasibility, and business viability. Business viability was particularly important to James and Duffy given the many different stakeholders in the healthcare field who often had competing priorities when it came to adopting—and paying for—new health technologies. To convince these different parties that any new solution would be worthy of embracing, the partners knew they would need strong clinical data that proved the value of the intervention.

Several weeks into their research, Duffy uncovered a landmark diabetes study conducted by the National Institutes of Health. A major multicenter clinical trial, the Diabetes Prevention Program (DPP) tested several different protocols in participants at high risk for developing type 2 diabetes (all were overweight and had prediabetes, meaning that they had blood glucose levels that were higher than normal). One

This case study was prepared by Samantha Madala, Stacey McCutcheon, Lyn Denend, and Marta Gaia Zanchi. Thank you to Adrian James for his contribution to this project.

protocol had shown to be remarkably successful, a “lifestyle modification” approach in which participants received personal coaching, education, and motivational counseling to help them lose a modest amount of weight by improving their diet and increasing their exercise. Across gender and race, participants in this group reduced their risk of developing type 2 diabetes by 58 percent. For individuals over the age of 60, who make up the largest portion of the diabetic population, the risk reduction was even greater at 71 percent.[4]

Duffy and James were impressed by the effectiveness of the behavioral interventions in the DPP. Even more importantly, they knew they had found the clinical evidence base from which they could begin to address diabetes prevention. “We could imagine an online version of the coaching and guidance provided in the DPP trial that would leverage human-centered design and digital technology. But we wouldn’t have to prove the value of those interventions. We wouldn’t have to run our own randomized controlled trial to have a starting point,” remembered James.[5] Instead, they could use the compelling results from the DPP as a foundation from which to build in both developing their offering and driving its adoption.

Going Deep in Diabetes

To start out, James and Duffy set aside the other chronic conditions they had been investigating and went deep on researching the need for improved diabetes prevention. Through this process, they learned that diabetes is a rapidly growing health problem that dramatically increases the risk of heart disease, nerve damage, amputations, blindness, kidney disease, and premature death.[6] Thirty million Americans or 9.4 percent of the population have diabetes, and another 84 million are considered prediabetic. Most people with prediabetes are unaware that they have the condition.[7] At the time, in 2012, diagnosed diabetes cost the US an estimated $176 billion in direct medical costs and an additional $69 billion in productivity loss.[8] Moved by the magnitude of the problem, James and Duffy became even more excited about developing a digital platform to disrupt the widespread progression from prediabetes to diabetes that affected so many people. Accordingly, they initiated a more detailed assessment of their idea relative to IDEO’s three lenses.

Desirability in Satisfying a Human Need

To assess the desirability of a digitally-delivered, preventative lifestyle intervention, James and Duffy launched questionnaires and in-home research, including one-on-one, in-person interviews with people who had been diagnosed with prediabetes. “We got right down to business and tried to feel out for sure whether this would be meaningful to them,” said James. The results of these efforts were highly encouraging and fueled their enthusiasm for pressing forward.

Technical Viability

In an effort to gauge the technical viability of their solution concept, they surveyed the technology landscape to determine what would be feasible. They also explored how to design a system with all the right components and that would integrate effectively with people’s current use of technology. As James explained, “We not only had to figure out how to translate the DPP interventions into a digital context, but actually evolve beyond that in order to make it accessible and engaging to millions of people while retaining the distinct elements that made it effective.” Recognizing that behavior change is difficult and that different people were likely to find different elements of the program motivating, James and Duffy started to map out a multi-component program that would blend hardware, software, and personal communication and support.

Participants in the Omada program get a cellular scale delivered to their door, as well as specialized software that helps them track food consumption, participate in interactive lessons on health and nutrition, and communicate with a professional health coach. Participants also get regular reminders and custom

feedback on their progress to help them stay on track, and are connected to an online support group of other participants to create a sense of community and provide encouragement.

Business Viability

As this work unfolded, the partners gained confidence about the desirability of their digitally-driven intervention, as well as the technical viability of creating a compelling offering. However, determining the best approach to achieving business viability was a bigger challenge. James and Duffy were aware that many digital health companies were opting to bypass traditional healthcare payment mechanisms in favor of "direct to consumer" marketing and payment models. While this route had the potential to be faster and easier than trying to convince traditional healthcare purchasers to cover a new technology-based offering, they did not believe it represented the best long-term approach for the company, which they eventually spun out of IDEO as Omada Health.

James and Duffy (who became Omada's President and Omada's CEO, respectively) felt strongly that the powerful clinical evidence demonstrating how effective a lifestyle change program could be in reducing the incidence of type 2 diabetes was a key differentiator for their technology. They conducted extensive research into healthcare payment policy and investigated payment precedents in the US to help guide their decision about the best business model to adopt. "It took a year to figure out how the dollars flow in healthcare," said Duffy.[9]

"We found that, in general, payers in the US healthcare system—the employers, health plans, and integrated delivery networks—are willing to pay for prevention when they have evidence of near-enough-term return on investment and a strong clinical evidence base," said James. "When we began researching precursors to chronic conditions, we found many that were compelling but lacked proof of a near-term ROI. Whereas in diabetes, the follow up from the DPP trial included multiple economic studies that showed a return within about a year and a half."

James continued, "Without treatment, nearly one third of people with prediabetes will go on to get type 2 diabetes within five years.[10] And that is linked to a significant and predictable increase in healthcare expenses. So we had a timeline, we had an increased expense, and we had a risk-bearing environment where payers are trying to avoid that expense." This combination of information persuaded the Omada team to pursue payment for their technology through more traditional healthcare channels. "If we were creating a product that looks, feels, and smells like something healthcare should provide to you," James said, "then we should stick to our guns and find a way to get it covered. So rather than ask consumers to pay for their own diabetes prevention, we decided to fight from inside the belly of the healthcare beast to create a little bit of change and disruption."

While the team eventually hoped to be covered by all major public and private insurers in the US, they recognized that this could take significant time and energy to achieve. Recalled James, "Reimbursement and medical policy across the US is influenced by the Centers for Medicare and Medicaid Services [CMS]. And CMS hadn't weighed in on diabetes prevention programs yet."

Accordingly, Omada decided to focus initially on developing a business-to-business model targeted at integrated delivery networks and self-insured employers. Because both of these types of entities bear the full cost of providing and paying for care for a well-defined population, the Omada team believed they should have a direct, vested interest in keeping their constituents well—that is, managing their prediabetes and preventing the costly onset of type 2 diabetes. Referencing self-insured employers specifically, James noted, "We thought that once you make a convincing argument to them about employee engagement and productivity, and lower annual healthcare expenditures backed up by data, then they'll choose to pay for prevention."

Favorable Policy Winds

As the Omada team wrestled with making and implementing these important business decisions, James and Duffy proactively monitored what was happening on the national healthcare policy front. They were keenly aware that changes in US payment policies and/or payment-related programs had the potential to dramatically help (or hinder) their plans for business viability.

As it turned out, several positive forces helped bolster the Omada approach. In 2010 Congress had authorized the Centers for Disease Control (CDC) to establish the National Diabetes Prevention Program (National DPP), a public-private initiative that created an infrastructure for the delivery of evidence-based lifestyle change programs to people at high risk for type 2 diabetes across the country. The initiative had several components, including raising awareness around prediabetes, recruiting organizations to deliver lifestyle intervention programs, and convincing insurers to pay for them. To ensure the quality of those programs, the National DPP also established the CDC Diabetes Prevention Recognition Program, which certified providers of lifestyle change programs and helped train coaches to ensure that standards and quality guidelines were achieved. [11]

One of first organizations to sign on was United Healthcare Group, the nation's largest insurer, which partnered with the national YMCA to develop and deliver a 16-session lifestyle intervention program conducted in a group setting.[12] The partnership established a valuable industry precedent for Omada Health. "Basically, United Healthcare Group was paying the YMCA to implement a 'brick and mortar' version of the interventions in the DPP," James recalled. "So it wasn't like we were the very first people to think of this concept—we were just the first people to begin doing it online, and potentially at a much larger scale."

There were also indications that Medicare might eventually reimburse diabetes prevention programs for at-risk seniors. In 2012, a pilot program was launched by the Department of Health and Human Services to evaluate the effectiveness and cost savings potential of these programs in the Medicare population, and Senator Al Franken introduced a bill (which passed in 2016) to get Medicare to reimburse for them.[13]

The CDC initiative, United Healthcare precedent, and likelihood of future CMS coverage encouraged Duffy and James to continue pursuing their model. "As long as our program met CDC quality standards, it seemed likely that insurers would eventually reimburse us," said James. In the end, such forces ended up validating the business-to-business and healthcare reimbursement models that today are at the heart of Omada's business viability strategy.

Looking Ahead

One of the first digital health offerings to be recognized by the CDC as meeting the evidence-based standards for the National DPP, Omada's outcomes-based pricing model means that the company is paid when at-risk individuals enroll in the program and when they achieve results. To date, Omada Health has partnered with more than 1,500 health plans, health systems, and employers across the country.[14]

Key Insights

- **Measures matter**
  Metrics and outcomes data are imperative for most digital health companies. Solutions backed by strong clinical evidence are fundamentally better equipped to achieve long-term business viability.

- **What's easy today may not make sense tomorrow**
  For a start-up, generating revenue is so important that it can be tempting to take the path of least

resistance. But, oftentimes, creating a sustainable business depends on making difficult (not easy) decisions and investing the time, energy, and resources needed to devise a more lasting solution.

- **Pay attention to policy**
  When it comes to choosing how you'll get paid, be sure to research, benchmark, and analyze the models chosen by companies that have come before you, and understand what made them successful (or not). And actively track and respond to any/all external forces with the potential to make (or break) the direction you choose. You can't necessarily control these powerful factors, but at least you won't be blindsided by them.

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