OMADA HEALTH: MAKING THE CASE FOR DIGITAL HEALTH

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Adrian James and Sean Duffy's founded Omada Health (Omada) in 2011 with the initial goal of using digital therapeutics and behavioral health interventions for patients with prediabetes. The data supporting this approach was strong: in 2002, the Diabetes Prevention Program (DPP) randomized control study concluded that the most effective treatment for prediabetes is prevention and behavioral intervention. However, James and Duffy observed a problematic gap between a surplus of data that confirmed the efficacy of intensive behavioral health counseling in diabetes, and the 86 million individuals with prediabetes who have not yet completed a DPP type program. James and Duffy believed that Omada's digital approach to scaling a validated DPP program could resolve a critical need and increase access to DPP for patients with prediabetes.

PIONEERING DIGITAL THERAPEUTICS AND DIGITAL BEHAVIOR CHANGE

Although digital health often refers to health apps and products, James and Duffy were determined to design a service to guide participants through an interactive journey that was integrated into their everyday lives. As James asserted,

> The day that our participants see us as a health app is the day of obsolescence. In my smartphone I've got like 10 different health apps, many of which I never click on. We're saturated in this world of tracking. If you go out and ask someone, "How meaningful are these apps to you?," I think many would say that they are something they're curious about and will try, but that they are not really baked into their lives.

Above all, the core mission of the company was to empower people to take ownership over their health and to reduce their risk of disease. In keeping with this philosophy, they named their company, "Omada," the Greek word for "group," which was reflective of their desire to bring people together in a journey toward diabetes prevention.

Some of the access barriers associated with in-person DPP were the time and expense required to travel to and attend these sessions. James and Duffy sought to mitigate these challenges and also asked themselves how they could engage individuals in a way that was scalable. The Omada DPP approach was a 16-week digital behavioral intervention that featured four core elements: educational modules and an evidence-based curriculum; health coaches; peer support and networking groups; and tools and food and activity trackers, which included a cell-chip enabled scale that automatically transmitted daily weigh-in data to Omada's health coaches and data scientists.

When individuals qualified for and joined the program, they accessed Omada's platform using either its online web, or a smartphone interface. Omada's DPP was split into two distinct phases: Foundations and Focus.

- *Foundations*: For the first 16 weeks, participants participated in the

Foundations Phase. In this stage, participants completed weekly lessons designed to reinforce habits, communicated with their virtual group, led by a professional, full-time health coach. Additionally, participants privately worked with their coach to address individual challenges. In this phase, there were four four-week chapters covering nutrition and healthy eating, physical activity, managing environmental stressors and sleep. These chapters were aimed at reinforcing lifelong habits.

- *Focus*: After the Foundations Phase, participants entered the eight-month Focus Phase, during which they had continued access to their health coach, initial cohort, and weekly lessons. Participant groups were then merged into larger cohorts so that individuals could have access to a wider range of support and experiences.

USING DATA TO DRIVE HEALTHY OUTCOMES

Omada aimed to collect measures in a way that was simplistic and effortless for participants, but also maintained clinical integrity and monitored clinically meaningful outcomes while doing so. The digital scale was easy for patients to use and served as a program integrity safeguard given that health coaches and data scientists instantly knew whether or not participants were weighing in. Consequently, Omada data scientists and health coaches were able to closely monitor any spikes in weight and then determine if the observed weight gain was an outlier or a sign that further intervention and health coaching was required. The health coach served as the "human touch" between the data scientists and participants, helping the scientists better understand user patterns and the nuances of the large data set they collected.

To symbolically capture the dedication to outcomes and data, the Omada office featured a live map of patient weigh-ins from across the country. As of June 2017, the map amassed a cumulative total of 18 million weigh-ins. By thoughtfully collecting these measurements, the company increased compliance and therefore facilitated a more effective data collection process.

Consistent with their evidence-driven beginnings, Omada was paid by their clients based on their outcomes. James and Duffy believed that this outcomes-based pricing model demonstrated their commitment to delivering results for participants and a return on investment for their clients, namely self-insured employers and a small number of health plans. As part of the program, Omada kept clients up to date on process via real-time, de-identified, aggregate reports. Furthermore, Omada published outcomes data to demonstrate program replicability. One study indicated that after 16 weeks, Omada participants lost 4–5% of their body weight and kept most of the weight off years after completing the program, thereby preventing the progression from prediabetes to diabetes over time.

THE CHALLENGE IN GOING TO SCALE

In the summer of 2017, Omada was eagerly waiting for the Center for Medicare & Medicaid Services (CMS) to release the Medicare Physician Fee Schedule which would include the final rules for the Medicare Diabetes Prevention benefit. James and Duffy were hopeful for a favorable outcome, which would include telehealth and digital delivery of DPP programs. If CMS added these programs to the fee schedule, Omada planned to deliver their program to Medicare beneficiaries starting January 1, 2018. Ruminating on the possibilities, Duffy added that "it was an amazing moment because Medicare had the potential to influence private medical policies," which would provoke others to say, "If Medicare is doing it, why don't we?" Essentially, if Medicare started to pay for diabetes prevention, it would help catalyze activity and growth for Omada.

In November 2017 the CMS revealed that it would reimburse for in-person DPP programs, but that it would not yet reimburse for telehealth and digital delivery of DPP programs. CMS asserted the reason was a lack of compelling evidence regarding clinical efficacy. This was not the decision that James and Duffy were hoping for and they had to quickly decide how to move the company forward.

1. If you were James and Duffy, what are your next steps following CMS's decision not to reimburse? What are the viable options or strategies for addressing CMS's concerns regarding clinical efficacy?