

Helmsley Charitable Trust awards the Jaeb Center ~\$5 million for virtual clinic study (n=300) with remote CGM onboarding and insulin dosing support - August 11, 2020

Trial to include type 1 and type 2 participants with involvement from [Cecelia Health](#), [DreaMed](#), and unspecified "national payer" evaluating clinical, psychosocial outcomes & cost-effectiveness; pilot study read out at [ATTD 2020](#)

The Helmsley Charitable Trust recently [announced](#) that it has awarded the Jaeb Center for Health Research Foundation just over \$5 million to fund an 300-person efficacy study that will evaluate a virtual diabetes specialty clinic model which incorporates remote CGM onboarding, insulin dosing advice, and mental health support. The six-month nationwide study will enroll CGM-naïve type 1s and type 2s receiving diabetes care for a primary care provider through an unspecified "national payer," who will also help with data analysis and economic outcomes. The virtual clinic team will include Cecelia Health's licensed psychologists, behavioral health coaches, and CDCESs who will provide remote CGM onboarding and insulin dosing support. Notably, in this study, the virtual care teams will use the DreaMed Advisor platform, centralizing data from CGM, SMBG, insulin pumps, and smart pens and providing decision support. The study will evaluate clinical and psychosocial outcomes, including CGM use over time, glycemic outcomes, participant-reported outcomes, healthcare utilization and cost, use of decision support tools, and the need for and impact of mental health services. According to the [press announcement](#), results will be shared by the Jaeb Center "within twelve months after trial conclusion" and by December 2022.

- **Results from a smaller Virtual Diabetes Specialty Clinic pilot study (funded by [Helmsley](#)) read out at ATTD 2020 in February.** Study participants (n=27 type 1s, n=7 type 2s) were remotely initiated on either FreeStyle Libre or Dexcom G6 and used the device an average of 95% of the time (6.9 days/week) during the 12-week study period. Participants saw a notable statistically significant -1.1% decline in A1c from 8.3% at baseline. The pilot study was also led by Jaeb, which contracted with Cecelia Health for support from its care teams, though the DreaMed-provided decision support will be a new addition for the larger study.
 - **Of course, ATTD 2020 happened right as COVID-19 began to spread in Europe.** Since then, we've seen hospitals and clinics shut down and device onboarding and routine visits move to a virtual setting. Just a few weeks ago, we [saw data](#) from Medtronic's MiniMed 670G virtual trainings during the early weeks of the pandemic that were quite encouraging with comparable glycemic results and better patient satisfaction and efficacy compared to in-person training. All of this is incredibly promising for the long-lasting use of virtual clinics and virtual tech training/onboarding, particularly given the potential for virtual clinics to improve rural access to diabetes tech and specialist care. We applaud the Helmsley Charitable Trust for its major investment and the Jaeb Center, Cecelia Health, and DreaMed for their work toward highlighting the efficacy of virtual care.
- **As described in our [AADE Technology Summit 2019 coverage](#),** Helmsley's ultimate goal is to understand how best to support the "whole person", including mental health and in a way that operates under a sustainable business model and benefits payers, CGM companies, and people with diabetes. The table below provides a further breakdown of the constituents. The involvement of a national payer in the larger study is particularly notable, as it will provide valuable claims and economic data. The financial model for this virtual diabetes clinic could go in many directions (e.g., non-profit, philanthropy-supported, company-funded, payer-supported), but will likely require proof of ROI to be sustainable.

Stakeholder	Benefit
Patient	Access to specialty care, technology, and coaching without location constraints
CGM Company	Expands market outside of brick-and-mortar special clinics, reduces customer service burdens, and improves patient CGM retention
Insurance	Taking care of the full person especially starting with mental health saves money, improves long-term patient retention, and makes the investment more cost-effective
Virtual Clinic	Various revenue streams from proof of concept, people with type 2 that will eventually need insulin, and CGM companies

Close Concerns' Questions

- When will the study begin enrolling? When will the study begin?
 - **HCT:** The study has started. Recruitment started in mid-August and first participants should be receiving their CGMs soon.
- Who is the national payer involved in the study?
 - **HCT:** They prefer to remain behind-the-scenes for now and we respect that, however we are thrilled to have them involved as we know that we will need payers to see the value in this model of care if it is to be sustainable.
- What states will participants be recruited from (at ADA 2019, we heard plans to enroll participants from at least five states)?
 - **HCT:** We are hoping to get participation from all 50 states. This is part of the reason we are using a national payer to help with recruitment from all parts of the United States.
- What will be the geographic and ethnic makeup of the participants?
 - **HCT:** We are sensitive to the need to have a study population that reflects the type 1 and type 2 communities in this country, and we will aim to achieve that in recruitment. We are hoping to have as wide of a scope as possible, including not only geography and ethnic makeup, but also socioeconomic status, age, and device usage. This is a fully virtual study and we believe it's a model that can work anywhere that people can reliably have internet access either through their cell phone or a computer.
- How will DreaMed's data and decision support tools affect the clinical workflow and outcomes?
 - **HCT:** Information is power. DreaMed processes a lot of information and makes it even more useable and therefore more powerful for helping people make better choices. We are hoping that the inclusion of DreaMed will be as seamless as possible. The clinical team will be viewing the participants glucose and insulin data as well as the decision support recommendations through the DreaMed portal. This should be similar to how the HCP and the person with diabetes can look at their diabetes data today.
- Who will ultimately fund something like the virtual specialty clinic?
 - **HCT:** Our vision is that if the model is proven to be well-liked by people living with diabetes, and helps them achieve better outcomes and lead healthier lives, we will also see a favorable economic impact and digital health companies as well as payers will get on board to help make this a new standard of care for people without access to specialty diabetes clinics.

--by Katie Mahoney, Albert Cai, and Kelly Close