

Nature Medicine publishes results reporting equal clinical outcome when using the DreaMed Advisor® compared with physicians from specialized academic diabetes centers

The diabetes research carried out by the NextDREAM Consortium group is a major international study to assess AI technology, published in Nature Medicine, marking an important milestone in the progress of remote diabetes solutions

Tel Aviv, Israel, August 2020 - The NextDREAM Consortium announces the publication in [Nature Medicine](#) of a multicenter, multinational, six-month study assessing the efficacy and safety of an automated AI-based decision-support system, the [DreaMed Advisor®](#), compared with physician-guided recommendations in a non-inferiority randomized controlled trial. The findings of the study concluded that glucose control was statistically similar after 6 months of frequent insulin pump titration, at 3-week intervals, either by using the DreaMed Advisor® or by physicians with diabetes expertise, as measured by percentage of time glucose levels were in range (70-180 mg/dL), in the very low range (below 54 mg/dL), and by reduction in HbA1c levels from baseline. No adverse severe events were reported in the arm that used the DreaMed Advisor® technology. [Funding for the study was provided by The Leona M. and Harry B. Helmsley Charitable Trust through DreaMed Diabetes Ltd.](#)

With more than a million people in the United States with Type I diabetes, a solution to ease their ability to conveniently manage their condition and frequently change their insulin treatment plan has been long-sought after, but not at the expense of safety and reliability. The increasing prevalence of diabetes,^{1,2} mounting shortage of specialized endocrinologists,³ and current COVID-19 reality that limits access to face-to-face visits with physicians, have raised the stakes even higher. Decision-support systems with proven clinical efficacy have the potential to deliver this assistance and elevate the quality of diabetes care by creating a virtual expert diabetes clinic that facilitates more frequent insulin adjustments in a cost-effective manner.

"This Nature Medicine publication is an important first step toward the implementation of AI-based decision-support technology as part of the standard way we manage the insulin therapy of people with diabetes," says Prof. Moshe Phillip, the Director of the Institute for Endocrinology and Diabetes at Schneider Children's MC in Israel & the nextDREAM Consortium Coordinator. "With the Advisor, healthcare providers will be able to use an easy and clinically effective decision-support tool that will give them more time to interact with their patients, while making regular clinics visits to the doctor more efficient. For people with diabetes, it will ultimately mean

¹ <https://www.idf.org/e-library/epidemiology-research/diabetes-atlas/134-idf-diabetes-atlas-8th-edition.html>

² Patterson CC, Harjutsalo V, Rosenbauer J, et al. Trends and cyclical variation in the incidence of childhood type 1 diabetes in 26 European centres in the 25 year period 1989-2013: a multicentre prospective registration study. *Diabetologia*. 2019;62(3):408-417

³ Vigersky RA, Fish L, Hogan P, et al. The clinical endocrinology workforce: current status and future projections of supply and demand. *J Clin Endocrinol Metab*. 2014;99(9):3112-3121

24/7 access to personalized medical advice, a kind of 'expert diabetes physician in your pocket,' that will bring people with type 1 diabetes greater balance and an improved quality of life."

"Managing type 1 diabetes can be very challenging for young people and their families, as well as healthcare providers, given the need to assess glucose levels and insulin requirements on a frequent basis in order to optimize diabetes control," says Lori Laffel MD, MPH, Chief of the Pediatric, Adolescent and Young Adult Section at the Joslin Diabetes Center and Professor of Pediatrics at Harvard Medical School in Boston, MA. "This study of 108 young people with type 1 diabetes, aged 10-21 years, indicates that frequent insulin adjustments transmitted remotely using an automated AI system can be as effective as expert physician dose adjustments, saving the healthcare provider time. Such an approach can be especially helpful during the current pandemic and can facilitate more timely insulin dose adjustments aimed at improving glycemic control."

"Mounting evidence proves maintaining glucose levels within the target range considerably improves long-term outcomes in people with type 1 diabetes. The Nature Medicine publication demonstrates the DreaMed Advisor® can be as safe and efficient as physicians with expertise in diabetes, providing a new AI-based solution to all health-care providers," says Prof. Tadej Battelino, MD, PhD, Head of the Department of Endocrinology, Diabetes and Metabolism at the University Children's Hospital, University Medical Center Ljubljana, and Chair of Pediatrics, Faculty of Medicine, University of Ljubljana. "Using the DreaMed Advisor® in routine diabetes practice can increase the level of diabetes care to a higher, more homogeneous level, and save time and resources, also in times when remote virtual diabetes management may be the safest solution."

Key Data Highlights

Glycemic control over six months:

- The percentage of time spent within target glucose range in the Advisor arm was statistically non-inferior to the physician arm ($P < 1e-7$).
- The percentage of readings below 54 mg per deciliter was statistically non-inferior between the Advisor and physician arms ($P < 0.0001$).
- A statistically significant reduction of 0.32% in mean glycated hemoglobin level from baseline to end of study (week 24) was observed in the Advisor arm (two-sided 95% CI of -0.55% to -0.08%, $P = 0.008$). The reduction from baseline to week 24 in the physician arm was 0.19% (two-sided 95% CI of -0.49% to 0.11%, $P = 0.22$).
- High satisfaction was expressed by physicians in the Advisor arm and 85% of them stated they would like to continue to use it as part of their routine practice.

The NextDREAM Consortium Group

Participating clinical sites and study team members: [University of Florida College of Medicine](#) in Gainesville, FL: Desmond Schatz MD, Michael Haller MD, Paul Hiers MD, Laura Jacobsen MD, Madison Smith PhD RN, Anastasia O'Neill ARNP, PhD, Jennifer Hosford MPH, Alexis Perry.

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